



ASH 2025 Updates for Support Groups

67th Annual Meeting & Exposition
Orlando, FL
December 6-9, 2025



**MYELOMA SUPPORT
GROUP**



- **What is ASH?**
- **Important Terminology**
- **How does the IMF get involved?**
- **Important ASH updates**
 - Frontline Therapy
 - Early Relapse
 - Late Relapse



What is ASH?



**MYELOMA SUPPORT
GROUP**

ASH: American Society of Hematology

ASH is the largest professional society serving both clinicians and scientists around the world who are working to conquer blood diseases.

Approximately 27,500 in person attendees and another 3,500 virtual!

Record number of abstracts submitted:

Over 9,000 (1000+ more than last year!)

Over 1,500 related to Myeloma!

including over 100 oral abstracts and 2 late breaking abstracts





Important Terminology



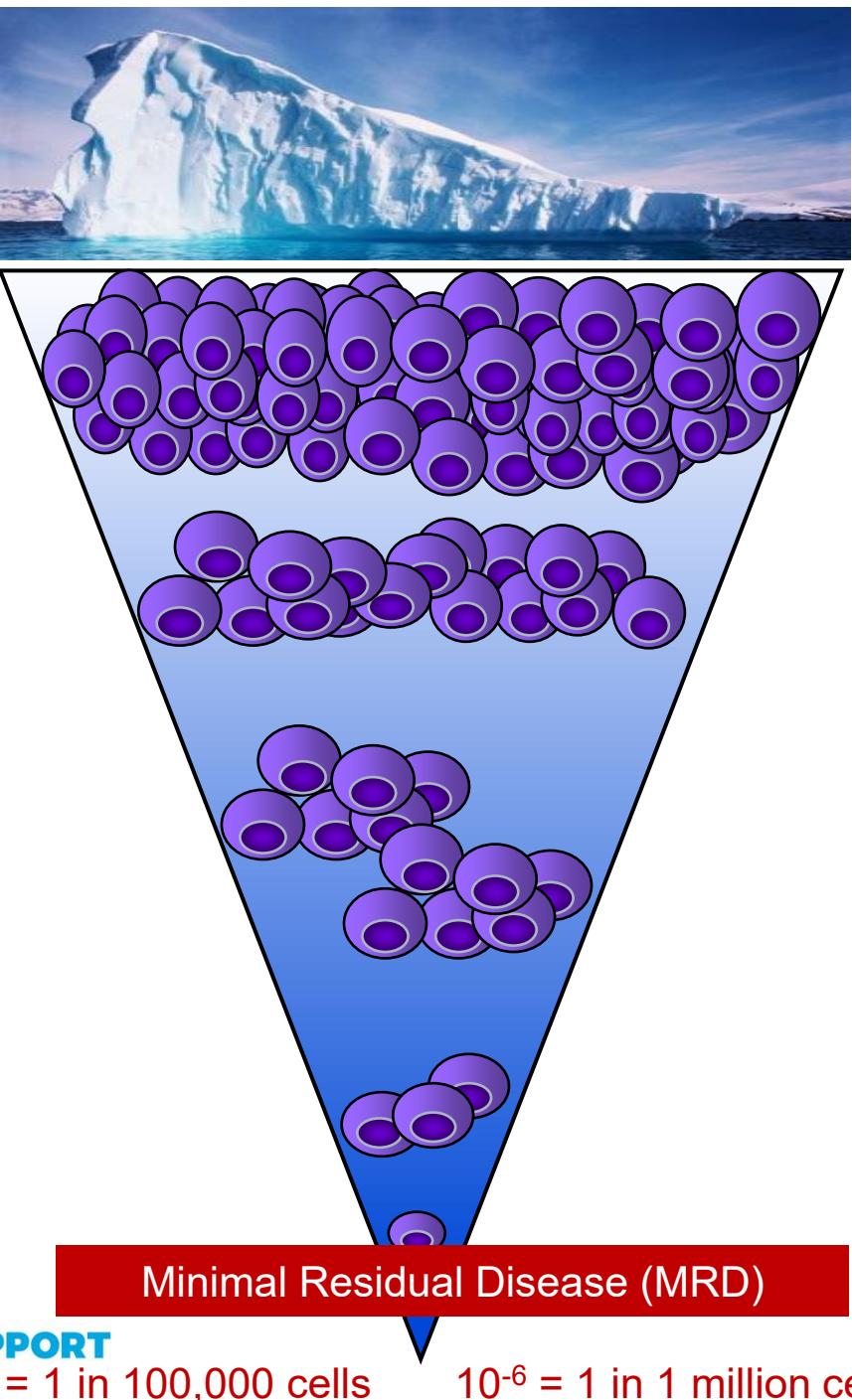
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Progressive Disease (PD)

Increase of at least 10% plasma cells in marrow or 25% in serum

Stable Disease (SD)

Response doesn't meet CR, VGPR, PR, or PD



Symptomatic Myeloma

At diagnosis

Partial response (PR)

At least a 50% reduction in M protein

Very good partial response (VGPR)

At least a 90% reduction in M protein

Near Complete Response (nCR)

At least a 95% reduction in M protein

Complete response (CR)

No M-protein found in serum; less than 5% in marrow

Stringent Complete Response (sCR)

No M-Protein found in serum or marrow

[Link to Glossary of Myeloma Terminology](#)

Clinical Trials (in simple terms)

Phase 1: (Average number of participants: 15-20)

GOAL-To determine the appropriate dose, administration method, and how the agent affects the human body

First step in transforming lab research to clinical care

Phase 2: (Average number of participants: >100)

GOAL-To determine whether an agent has activity against a specific cancer type

Using the dose determined to be safe in Phase 1 trials, evaluate effectiveness & safety data

Phase 3: (Average number of participants: Hundreds to thousands)

GOAL-To determine whether a treatment is effective compared to current standard

Usually randomized to control group (no placebo-standard of care) vs investigational arm

Phase 4: Post FDA approval, various goals

Real World Data



How does the IMF Get Involved?



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IMF Myeloma Voices at ASH 2025



**Patients, Care Partners,
Nurses,
Support Group Leaders...
Our Voices Matter!**

Follow the Myeloma Voices at ASH team on social media and read blogs about their experiences and impressions from attending ASH

[Myeloma Voices at ASH Webpage](#)

Myeloma Voices at ASH Facebook Live with Dr. Joe



IMF Chief Medical Officer Dr. Joseph Mikhael and our Myeloma Voices at ASH team went live on Facebook on the evening of Monday, December 8, to discuss the key myeloma research takeaways from the 2025 American Society of Hematology Meeting.

[Replay](#)

ASH 2025: IMF WEBINARS

THE IMWG CONFERENCE SERIES: MAKING SENSE OF TREATMENT

December 17, 2025 | 3pm PST / 6pm EST



DONNA CATAMERO,
ANP-BC, OCN, CCRC



SAGAR LONIAL, MD,
FACP, FASCO



TOM MARTIN, MD



JOSEPH MIKHAEL, MD,
FRCPC, FACP, FASCO

TOP MYELOMA RESEARCH PRESENTED AT ASH

January 7, 2026 at 3:00pm PST / 6:00pm EST



JOSEPH MIKHAEL, MD,
FRCPC, FACP
IMF Chief Medical Officer



ROSE SIMON
Maitland/Central Florida
Support Group



JIM SHOEMAKER
Mid-South Multiple Myeloma
Support Group



ROBIN TUOHY
IMF VP, Patient Support



JILL ZITZEWITZ, PhD
Central MA Multiple Myeloma
Support Group



The Myeloma Expert Perspective

Replay

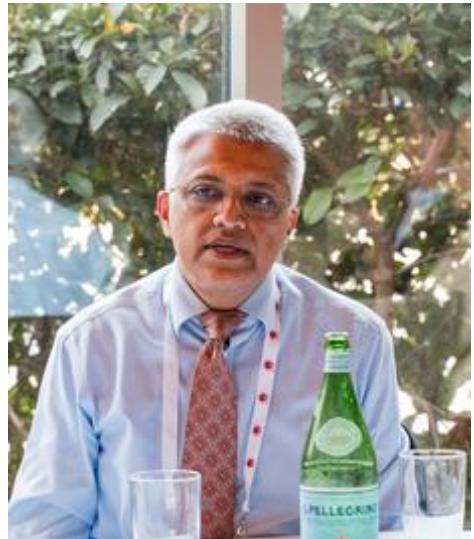


MYELOMA SUPPORT
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The Patient Perspective

Replay

IMF's Scientific Advisory Board





Key ASH Research Updates



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ASH Updates – Three Main Important Topics

**Frontline
Therapy**

**Early
Relapse
(1-3 Prior Lines)**

**Late
Relapse
(4+ Prior Lines)**

Frontline Therapy

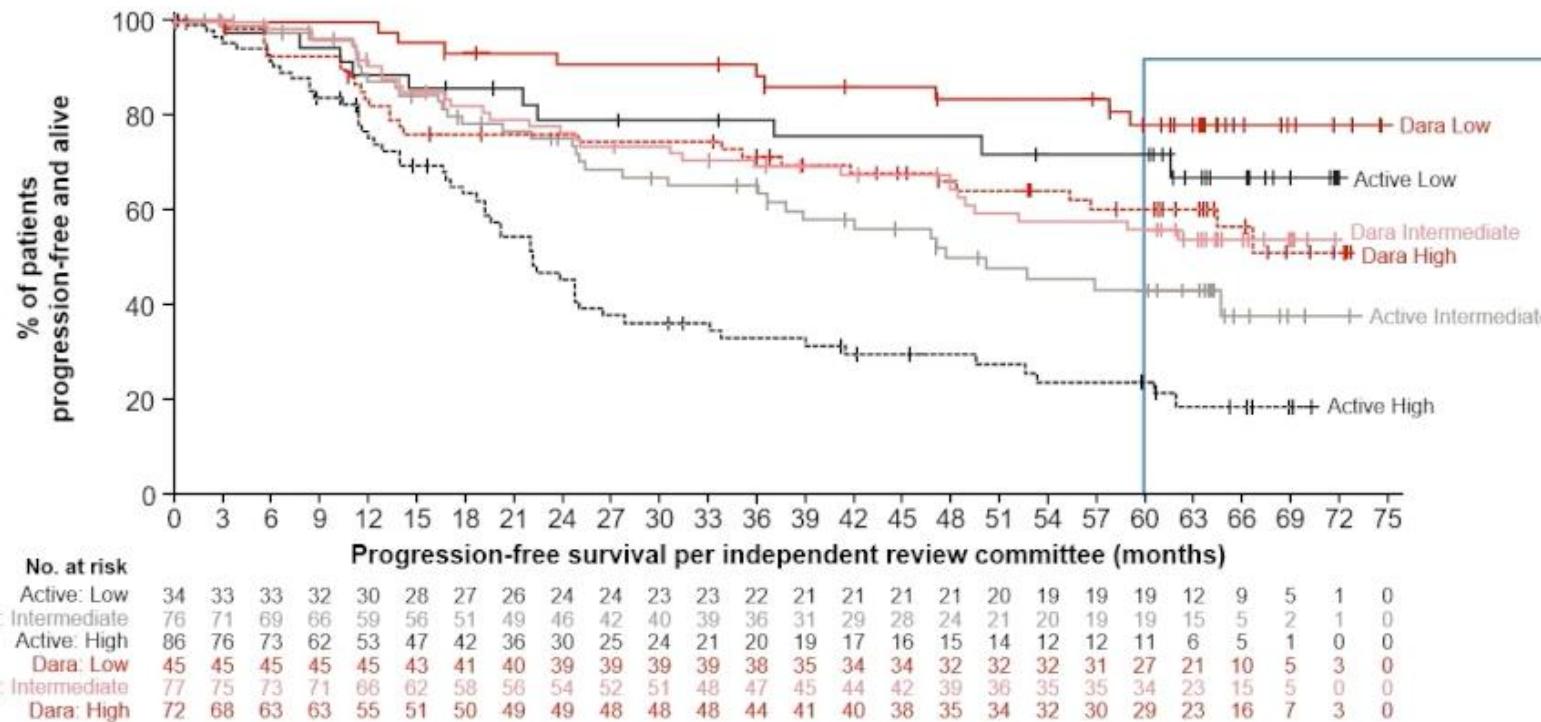
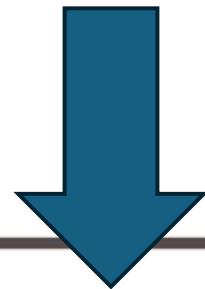
1. Smoldering MM – AQUILA (#372)
2. BENEFIT Trial – Isa-VRD (#368)
3. Teclistamab-Daratumumab (#367)
4. Dual target fastcar frontline (#258)
5. Linvoseltamab post induction (#248)

Daratumumab Monotherapy Versus Active Monitoring in Patients With High-Risk Smoldering Multiple Myeloma: AQUILA Outcomes Based on Mayo 2018/IMWG 2020 Risk Stratification, IMWG Scoring, and Age

Peter M Voorhees,¹ Meletios A Dimopoulos,² Yael C Cohen,³ Fredrik Schjesvold,⁴ Vania Hungria,⁵ Irwinderdeep Sandhu,⁶ Jindriska Lindsay,⁷ Ross I Baker,⁸ Kenshi Suzuki,⁹ Hiroshi Kosugi,¹⁰ Mark-David Levin,¹¹ Meral Beksac,¹² Keith Stockerl-Goldstein,¹³ Hila Magen,¹⁴ Albert Oriol,¹⁵ Gabor Mikala,¹⁶ Gonzalo Garate,¹⁷ Koen Theunissen,¹⁸ Ivan Spicka,¹⁹ Anne K Mylin,²⁰ Simon Hallam,²¹ Sara Bringhen,²² Katarina Uttervall,²³ Bartosz Pula,²⁴ Abdullah M Khan,²⁵ Eva Medvedova,²⁶ Jing Christine Ye,²⁷ Andrew J Cowan,²⁸ Philippe Moreau,²⁹ María-Victoria Mateos,³⁰ Hartmut Goldschmidt,³¹ Diego Vieyra,³² Ashta Raval,³³ Linlin Sha,³⁴ Liang Li,³⁴ Els Rousseau,³⁵ Robyn M Dennis,³⁶ Robin L Carson,³² S Vincent Rajkumar³⁷

¹Atrium Health/Levine Cancer Institute, Wake Forest University School of Medicine, Charlotte, NC, USA; ²School of Medicine, National and Kapodistrian University of Athens, Athens, Greece; Korea University, Seoul, South Korea; ³Tel-Aviv Sourasky (Ichilov) Medical Center, Tel Aviv Israel; Gray Faculty of Medical & Health Sciences, Tel Aviv University, Tel Aviv, Israel; ⁴Oslo Myeloma Center, Oslo University Hospital, Oslo, Norway, and KG Jebsen Center for B Cell Malignancies, University of Oslo, Oslo, Norway; ⁵Clinica Médica São Germano, São Paulo, Brazil; ⁶Cross Cancer Institute, Edmonton, AB, Canada; ⁷East Kent Hospitals University NHS Foundation Trust, Kent and Canterbury Hospital, Canterbury, UK; ⁸Perth Blood Institute, Murdoch University, Perth, Australia; ⁹Japanese Red Cross Medical Center, Tokyo, Japan; ¹⁰Ogaki Municipal Hospital, Ogaki City, Japan; ¹¹Albert Schweitzer Hospital, Dordrecht, the Netherlands; ¹²Ankara University, Ankara, Turkey; ¹³Washington University School of Medicine, St. Louis, MO, USA; ¹⁴Chaim Sheba Medical Center, Ramat-Gan, Israel; Sackler Faculty of Medical and Health Sciences, Tel Aviv University, Israel; ¹⁵Institut Català d'Oncologia and Institut Josep Carreras, Hospital Germans Trias i Pujol, Badalona, Barcelona, Spain; ¹⁶South Pest Central Hospital, National Institute for Hematology and Infectious Diseases, Budapest, Hungary; ¹⁷Hospital Alemán, Buenos Aires, Argentina; ¹⁸Jessa Hospital, Hasselt, Belgium; ¹⁹Charles University and General Hospital, Prague, Czech Republic; ²⁰Rigshospitalet, University of Copenhagen, Copenhagen; ²¹St Bartholomew's Hospital, London, UK, and Queen Mary University of London, London, UK; ²²SSD Clinical Trials in Oncol-ematologia e Mieloma Multiplo, AOU Città della Salute e della Scienza di Torino, Turin, Italy; ²³Medical Unit Hematology, Karolinska University Hospital, Stockholm, Sweden; ²⁴Institute of Hematology and Transfusion Medicine, Warsaw, Poland; ²⁵The Ohio State University Comprehensive Cancer Center, Columbus, OH, USA; ²⁶Knight Cancer Institute, Oregon Health and Science University, Portland, OR, USA; ²⁷MD Anderson Cancer Center, University of Texas, Houston, TX, USA; ²⁸Fred Hutchinson Cancer Center, University of Washington, Seattle, WA, USA; ²⁹University Hospital Hôtel-Dieu, Nantes, France; ³⁰University Hospital of Salamanca, IBSAL, and Cancer Research Center, IBMCC, Salamanca, Spain; ³¹Internal Medicine V, Hematology, Oncology and Rheumatology, GMMG Study Group, Heidelberg University Hospital and National Center for Tumor Diseases, Heidelberg, Germany; ³²Johnson & Johnson, Spring House, PA, USA; ³³Johnson & Johnson, Raritan, NJ, USA; ³⁴Johnson & Johnson, Shanghai, China; ³⁵Johnson & Johnson, Beerse, Belgium; ³⁶Johnson & Johnson, Wayne, PA, USA; ³⁷Division of Hematology, Mayo Clinic, Rochester, MN, USA

AQUILA: IMWG 2020 Subgroups: PFS



60-month PFS rates, %:

IMWG 2020 Risk group	Daratumumab	Active monitoring
Low	78.2	71.6
Intermediate	56.2	42.9
High	60.4	23.6

PFS active monitoring vs daratumumab monotherapy, high-risk group:
62.8% vs 37.5% events
HR 0.36 (95% CI: 0.23, 0.58)

Daratumumab monotherapy showed a PFS benefit vs active monitoring across IMWG 2020 risk subgroups, with the largest benefit observed in the high-risk subgroup

IMWG 2020 (aka Mayo 2018 or 20-2-20) risk stratification: BMPC >20%, monoclonal spike >2 g/dL, serum I/U FLC ratio >20. 0 factors=low risk; 1 factor=intermediate risk; ≥2 factors=high risk

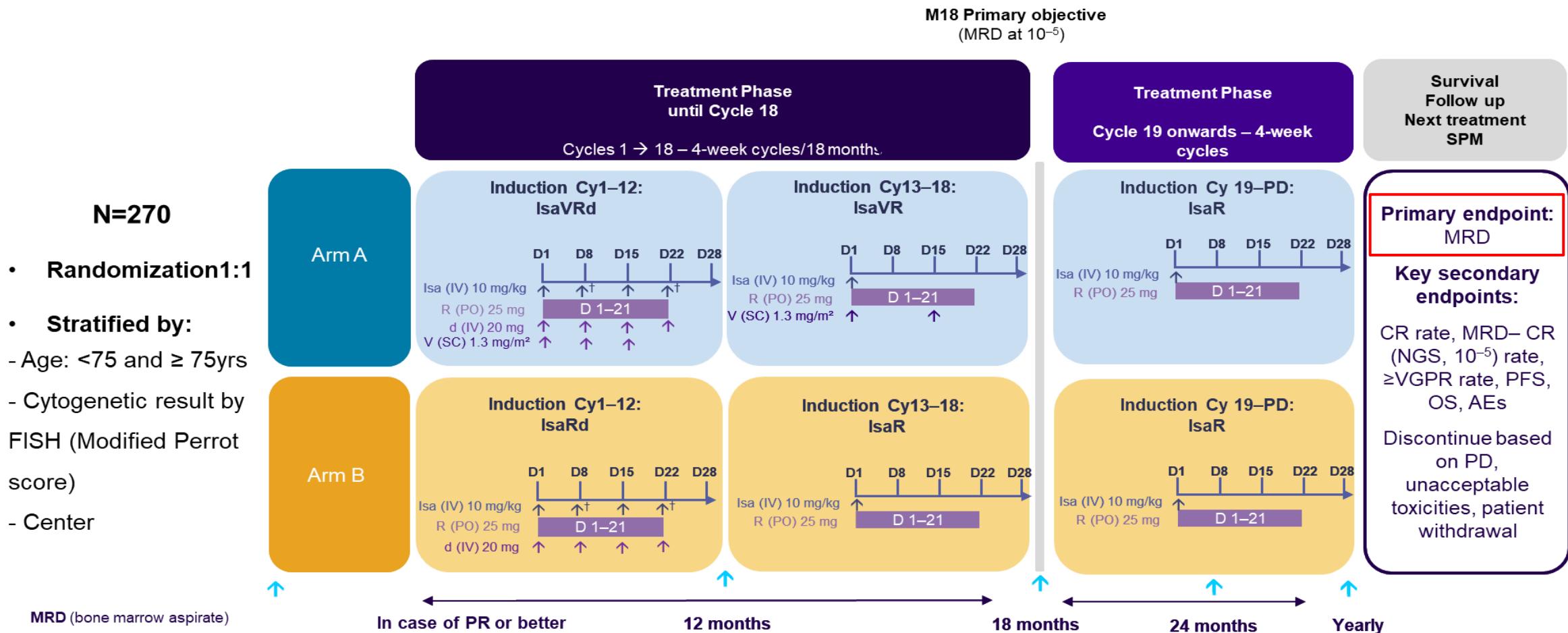
BMPC, bone marrow plasma cells; FLC, free light chain; IMWG, International Myeloma Working Group; PFS, progression-free survival; SC, subcutaneous; SMM smoldering multiple myeloma.



Sustained minimal residual disease in BENEFIT phase 3 randomized study of Isatuximab plus Lenalidomide and Dexamethasone with Bortezomib (Isa-VRd) versus IsaRd in newly diagnosed transplant ineligible Multiple Myeloma (IFM 2020-05)

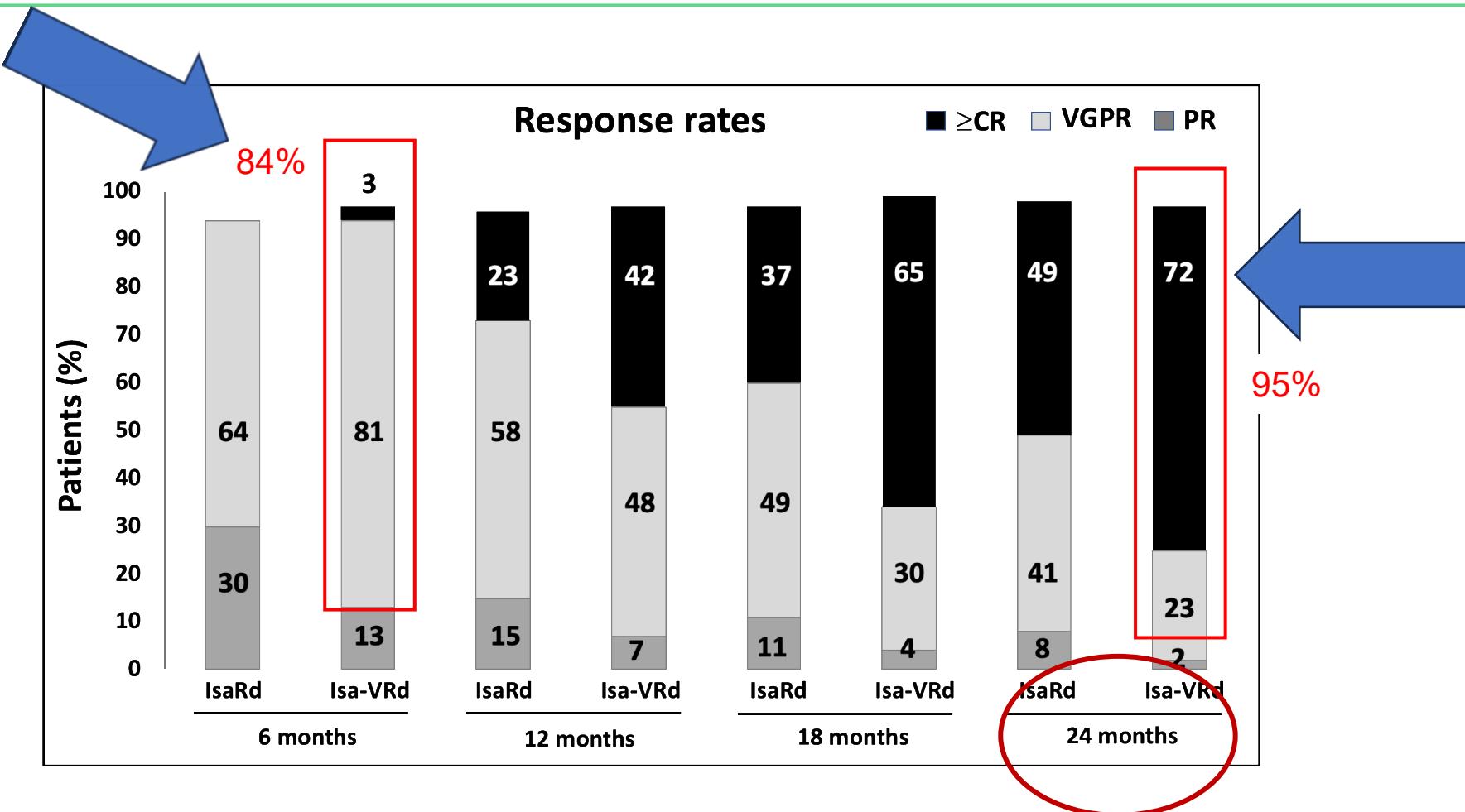
Arthur Bobin, Jerome Lambert, Jill Corre, Salomon Manier, Aurore Perrot, Lionel Karlin, Murielle Roussel, Noemie Bigot, Omar Benbrahim, Olivier Allangba, Philippe Rey, Véronique Dorvaux, Marguerite Vignon, Virginie Roland, Réda Garidi, Jean-Noel Bastie, Marie-Lorraine Chretien, Sophie Godet, Lydia Montes, Brieuc Chere, Souhila Ikhlef, Anne Vekhoff, Thomas Chalopin, Borhane Slama, Kamel Laribi, Claire Dingremont, Christophe Roul, Valentine Richez-Olivier, Clara Mariette, Sophie Rigaudeau, Claire Calmettes, Mamoun Dib, Mourad Tiab, Laure Vincent, Jacques Delaunay, Jean-Pierre Marolleau, Pascal Godmer, Sabrina Maheo, Anais, Schavgoulidze, Laurent Frenzel, Ronan Le Calloch, Emilie Chalayer, Helene Gardeney, Margaret Macro, Bruno Royer, Stephanie Harel, Olivier Decaux, Bertrand Arnulf, Karim Belhadj, Cyrille Touzeau, Mohamad Mohty, Aurelie Gontier, Philippe Moreau, Thierry Facon, Cyrille Hulin, Xavier Leleu

Study design: Isa-VRd vs Isa-Rd in Ti NDMM



[†]Cycle 1 only. CR, complete response; Cy, cycle; d, dexamethasone; D, day; Isa, isatuximab; M, month; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; NGS, next generation sequencing; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PR, partial response; R, lenalidomide; SPM, second primary malignancy; Ti, transplant-ineligible; V, bortezomib; VGPR, very good partial response.

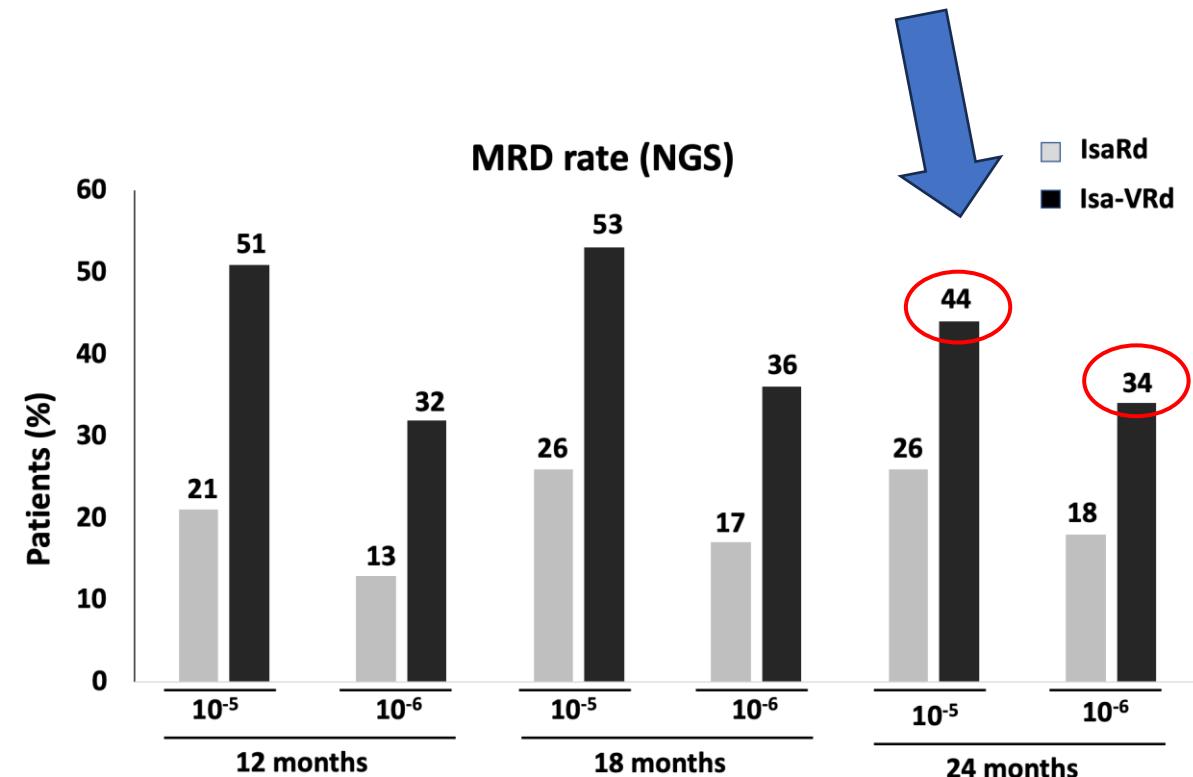
Depth of response at 12, 18 and 24 months - ITT Population



Isa-VRd resulted in deep response rates, including $\geq\text{CR}$ rate, at all timepoints

MRD– rate at 12, 18 and 24 months – ITT population

	IsaRd (n=135)	Isa-VRd (n=135)	OR (95%CI), p-value
At 12 months			
MRD- 10^{-5}	29 (21) [15-29]	69 (51) [42-60]	3.88 (2.27 - 6.62), <0.0001 ⁺
MRD- 10^{-6}	18 (13) [8-20]	43 (32) [24-40]	2.97 (1.6 - 5.5), 0.0005 ⁺
At 18 months			
MRD- 10^{-5}	35 (26) [19-34]	71 (53) [44-61]	3.16 (1.89 - 5.28), <0.0001
MRD- 10^{-6}	23 (17) [11-24]	49 (36) [28-45]	2.74 (1.54 - 4.87), 0.0006 ⁺
At 24 months			
MRD- 10^{-5}	35 (26) [19-34]	59 (44) [35-53]	2.26 (1.34 - 3.79), 0.002
MRD- 10^{-6}	24 (18) [12-25]	46 (34) [26-43]	2.39 (1.35 - 4.22), 0.003



Isa-VRd resulted in a significant improvement in the MRD at 24 months at 10^{-5} and 10^{-6} in the ITT population

MRD was performed on bone marrow aspiration in patients at least in \geq PR for the primary endpoint timepoint at 18 months. In ITT analysis, the patients with primary refractory disease, stable disease and minor response, along with patients failing MRD analysis, will be considered as patients with MRD positive at 10^{-5} . The MRD test was centrally and primarily determined by next generation sequencing (NGS) with a 10^{-5} sensitivity (Pr Avet Loiseau / Pr Corre, Toulouse Oncopole, France). In case of failure to perform MRD by NGS, MRD assessment was then performed centrally using multiparametric flow cytometry (MFC) with a 10^{-5} sensitivity (Dr Francois Vergez, Toulouse Oncopole, France)²¹. Next Generation Sequencing was performed using the Food and Drug Administration-approved Clonoseq 2.0™ assay in accordance with IMWG guidelines on assessment of MRD²⁰. Limit of Detection (LOD) and MRD status were determined using Adaptive's validated algorithms for the clonoSEQ V2.0 assay. MRD was assessed on the basis of IMWG recommendations.

MRD results are compared between treatment groups and treatment effect is assessed by odds ratio and 95% confidence interval using a mixed logistic regression with treatment as the explanatory variable and adjusting for randomization stratification factors. Interaction test are maximum likelihood test of an interaction term included in a logistic regression model. Square represents the estimated OR, and horizontal bars correspond to 95% CI. All statistical test used are two-sided with no correction for multiple comparisons.

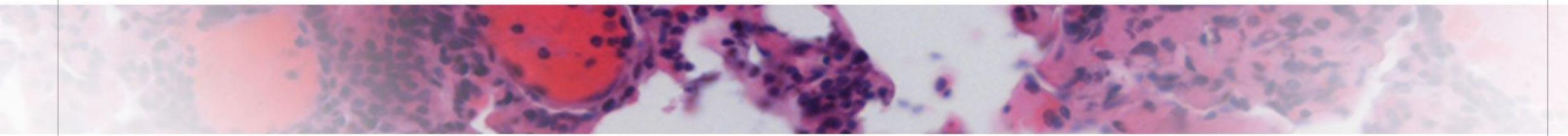
HRMM definition according to the GCS. Fourteen patients (Isa-VRd n=6 and IsaRd n=7) failed to have cytogenetic analyzed and were classified as non-HR in the ITT analysis.

Sustained negative MRD \geq 12 months (12-24 months). MRD negative at 12, 18 and 24 months. Sustained negative MRD 18-24 months. MRD negative at 18 and 24 months.

CI, confidence interval; FISH, fluorescence *in situ* hybridization; GCS, international genomic staging consensus; HR, high-risk; IMS, international myeloma society; ITT, intention-to-treat; MRD, minimal residual disease; NGS, next generation sequencing; no., number; %, percentages; s., sustained.



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Helping hematologists conquer blood diseases worldwide



A phase 2 study of teclistamab in combination with daratumumab in elderly patients with newly diagnosed multiple myeloma: the IFM2021-01 TecLille trial, cohort A

S. Manier, J. Lambert, M. Macro, T. Chalopin, M. Dib, A. Rumpler, J. Gay, J.-N. Bastie, C. Jacquet, C. Sonntag, L. Vincent, A. Perrot, C. Mariette, L. Montes, S. Rigaudeau, N. Bigot, M. Doyle, D. Santra, P. Smirnov, C. Albrecht, C. Touzeau, J. Corre, P. Moreau, H. Avet-Loiseau, C. Hulin, X. Leleu, T. Facon

Abstract #367

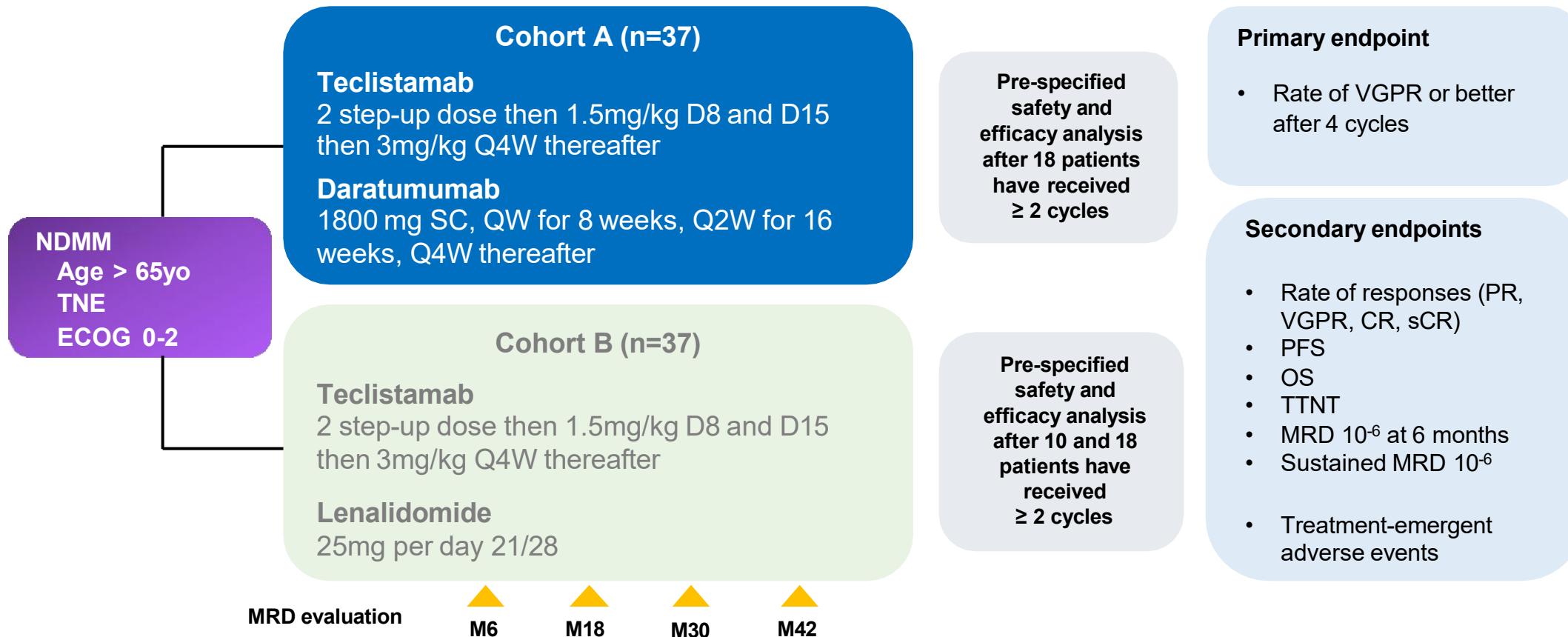


ASH 2025, Orlando



IFM 2021-01 TecLille - Study design

Phase 2 study of Tec-Dara and Tec-Len in TNE NDMM (n = 74)



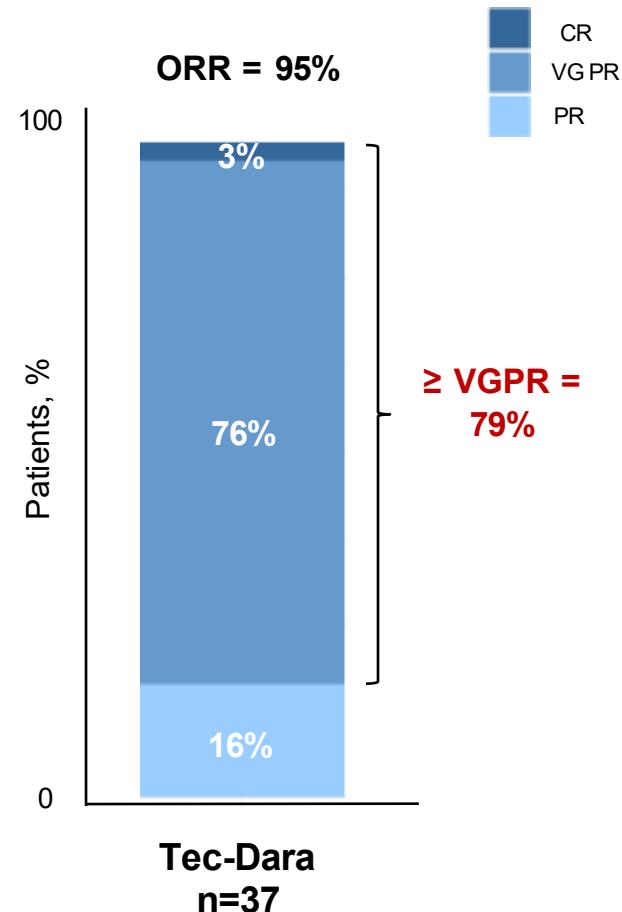
Current amendment:

Teclistamab 3mg/kg Q8W after C13 if CR or better and treatment interruption if 2-years sustained MRD -

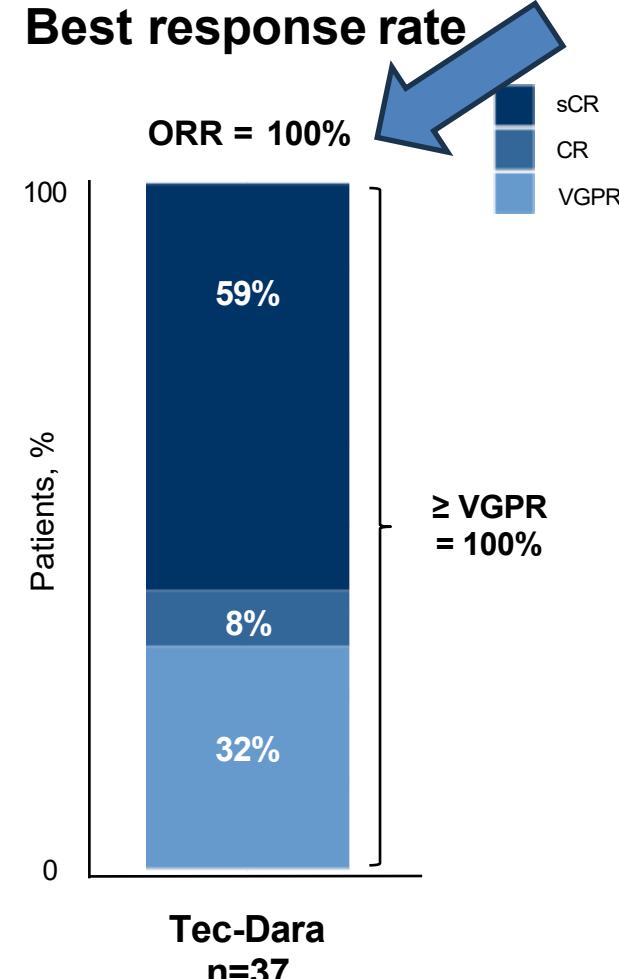
NCT05572229

IFM 2021-01 TecLille – cohort A: Tec-Dara Response rates

VGPR rate after 4 cycles*



Best response rate

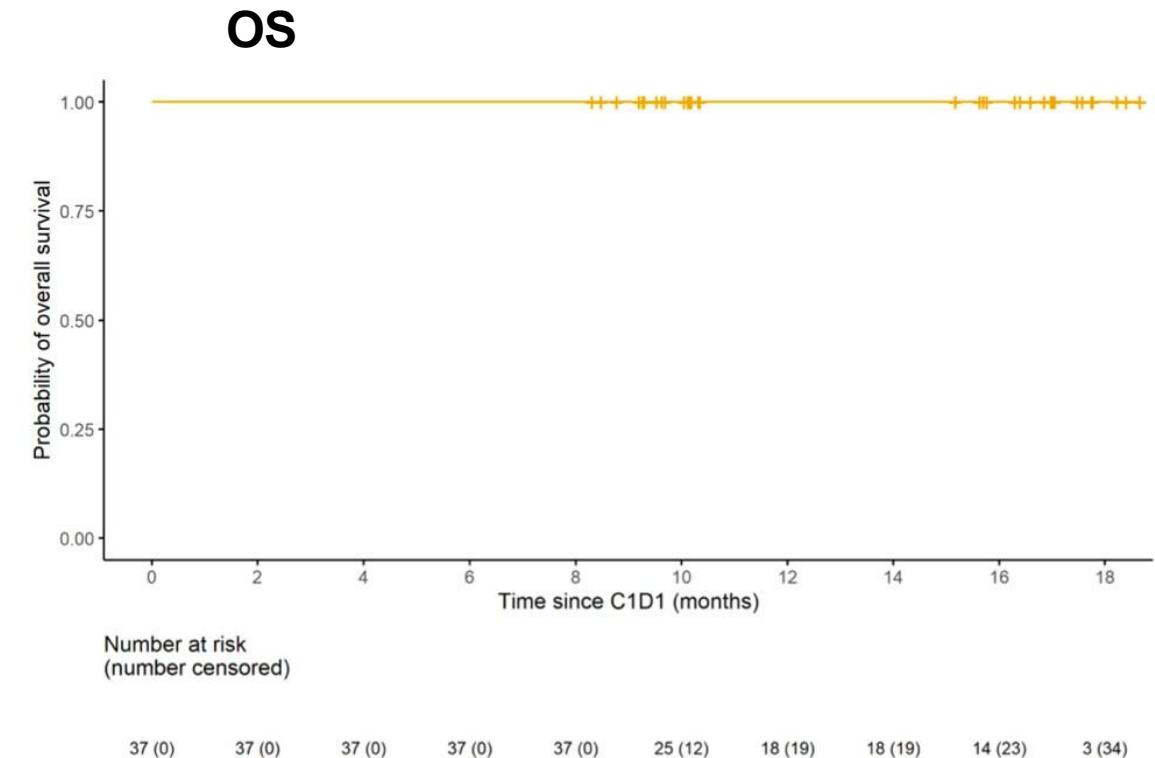
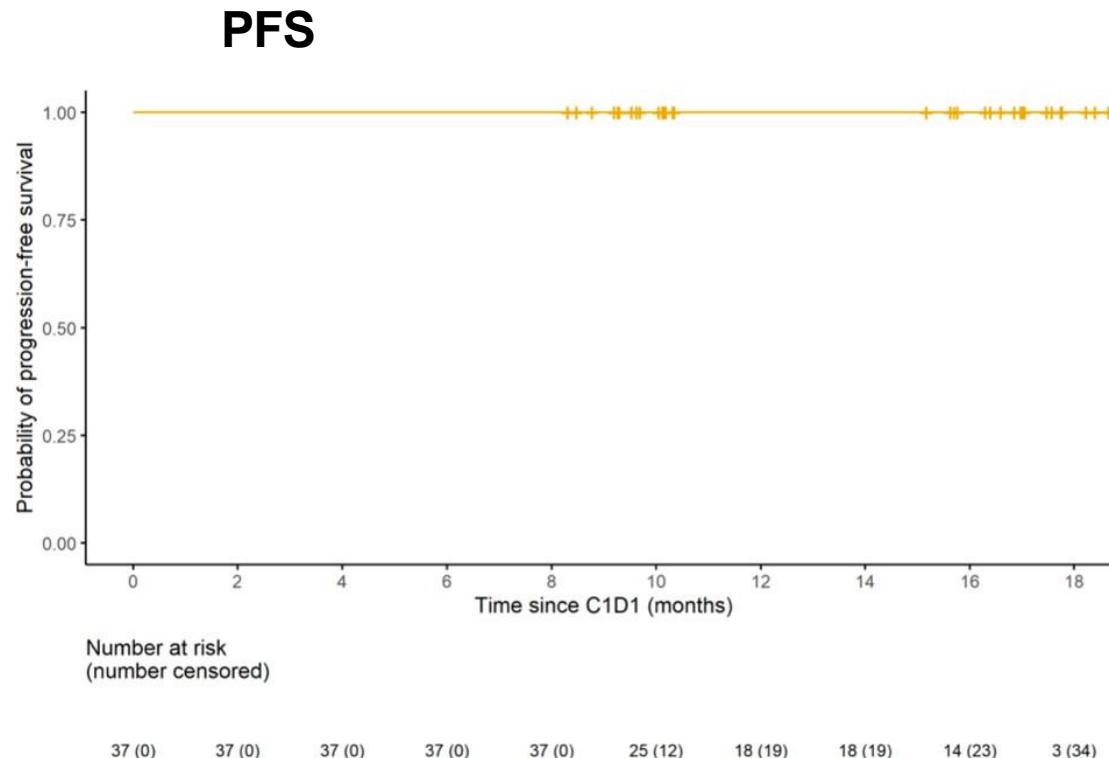


* primary endpoint

All patients achieved VGPR or better at best response

IFM 2021-01 TecLille – cohort A: Tec-Dara PFS and OS

Median follow up time = 10.3 months



No event of progression or death occurred

A Dual Targeting BCMA and CD19 FasTCAR-T (GC012F/AZD0120) as First-line Therapy for Newly Diagnosed Multiple Myeloma

Juan Du,^{*1} Wanting Qiang,¹ Jing Lu,¹ Yanchun Jia,¹ Haiyan He,¹ Jin Liu,¹ Pei Guo,¹ Ying Yang,¹ Zhongyuan Feng,¹ Lina Jin,¹ Xiaoqiang Fan,¹ Nina Shah,² Qi Zhang,³ Lianjun Shen,³ Jia Liu³

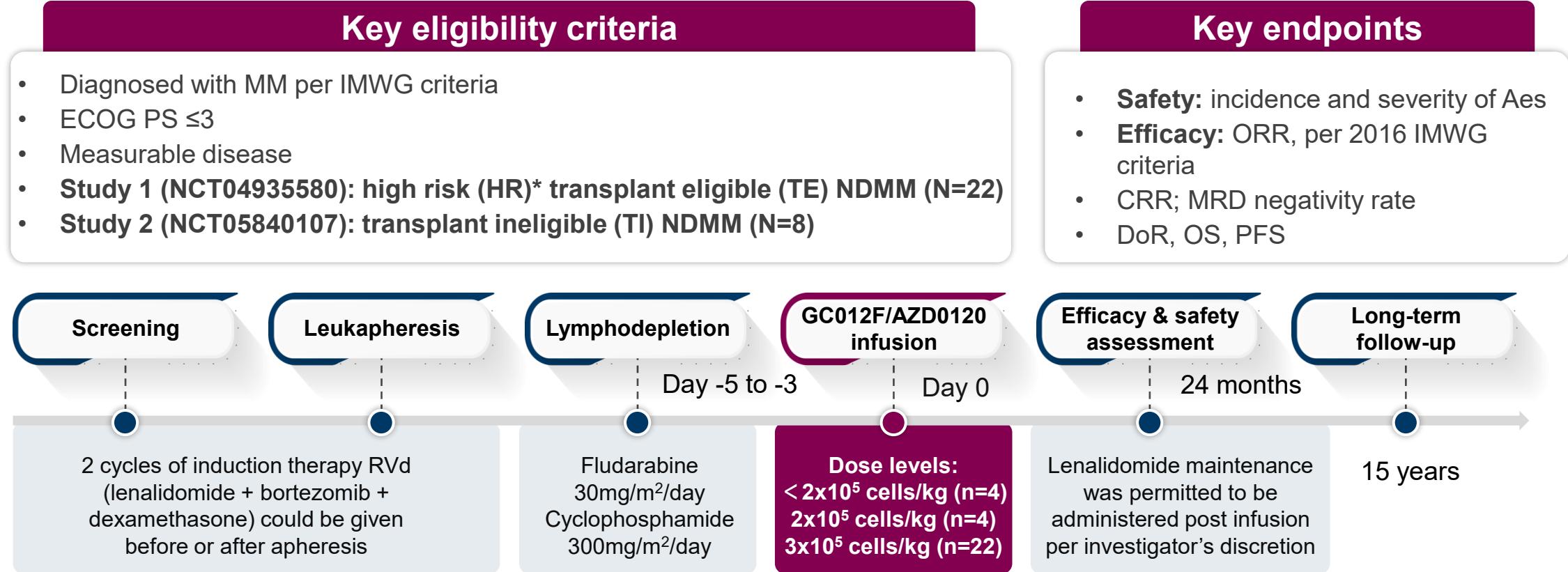
¹Department of Hematology, Myeloma & Lymphoma Center, Shanghai Changzheng Hospital, Shanghai, China

²AstraZeneca, Gaithersburg, MD, USA

³Gracell Biotechnologies Ltd., Shanghai, China

Study design

Two Phase 1 studies in NDMM

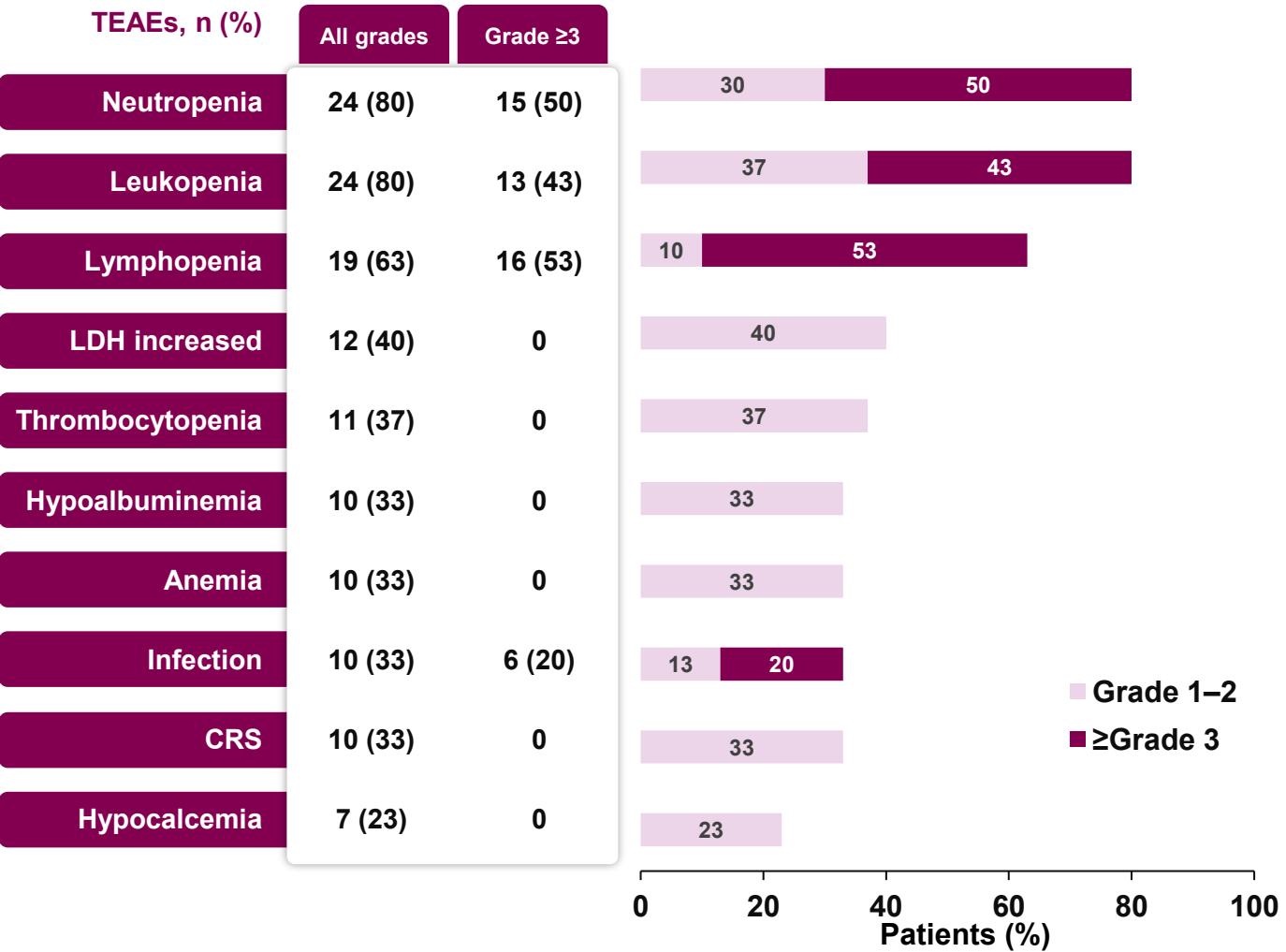


* High-risk was defined as meeting at least one of the following: a) R-ISS stage II or III; b) High-risk cytogenetics: del17p, t(4;14), t(14;16), or 1q21 ≥ 4 copies; c) Extramedullary disease; d) IgD or IgE subtype; e) High-risk definition according to mSMART3.0; f) LDH $>$ the upper limit of normal.

IMWG: International Myeloma Working Group; ECOG PS: Eastern Cooperative Oncology Group Performance Status; AE: Adverse events; ORR: Overall response Rate; CRR: Complete Response Rate; MRD: Minimal Residual Disease; PFS: Progression Free Survival; DOR: Duration of Response; OS: Overall Survival.

Safety profile: TEAEs

- GC012F was well tolerated and mostly low-grade CRS
- Grade 1 CRS: 30% (9/30), grade 2 CRS: 3% (1/30), grade ≥ 3 CRS: 0
 - Four patients with CRS were treated with tocilizumab
 - Median time to onset: 8 days (range, 6–18 days)
 - Median duration: 2 days (range, 1–8 days)
- No ICANS or IEC-HS or IEC-EC observed
- No delayed neurotoxicities or secondary primary malignancies observed to date

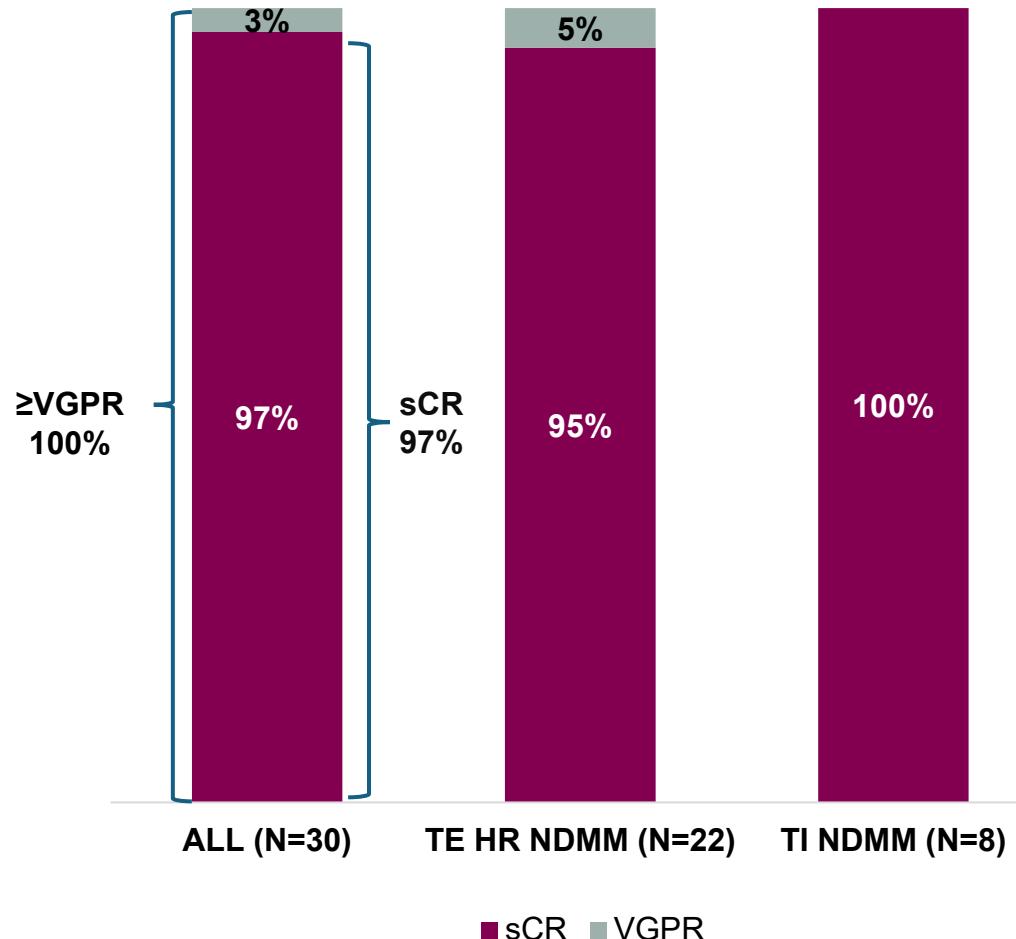


AEs were graded according to CTCAE v5.0.

AE, adverse event; ASTCT, American society for transplantation and cellular therapy; CRS, cytokine release syndrome, graded by ASTCT consensus; CTCAE, common terminology criteria for adverse events; ICANS, immune effector cell-associated neurotoxicity syndrome, graded by ASTCT consensus; IEC-EC, immune effector cell-associated encephalopathy; IEC-HS, immune effector cell-associated hemophagocytic syndrome; LDH, lactate dehydrogenase; TEAE, treatment-emergent adverse event.

Juan Du, MD, PhD

100% ORR in both cohorts



- Fast and deep responses were achieved in both groups
- As of October 15, 2025, the median follow-up time since diagnosis was 36.5 months (19.6–53.9)
- ORR=100% (30/30):**
 - 100% \geq VGPR
 - 97% (29/30) sCR (1 VGPR patient still in response)
- Median time to first response post infusion was 28 days
- Median time to best response post infusion was 68 days

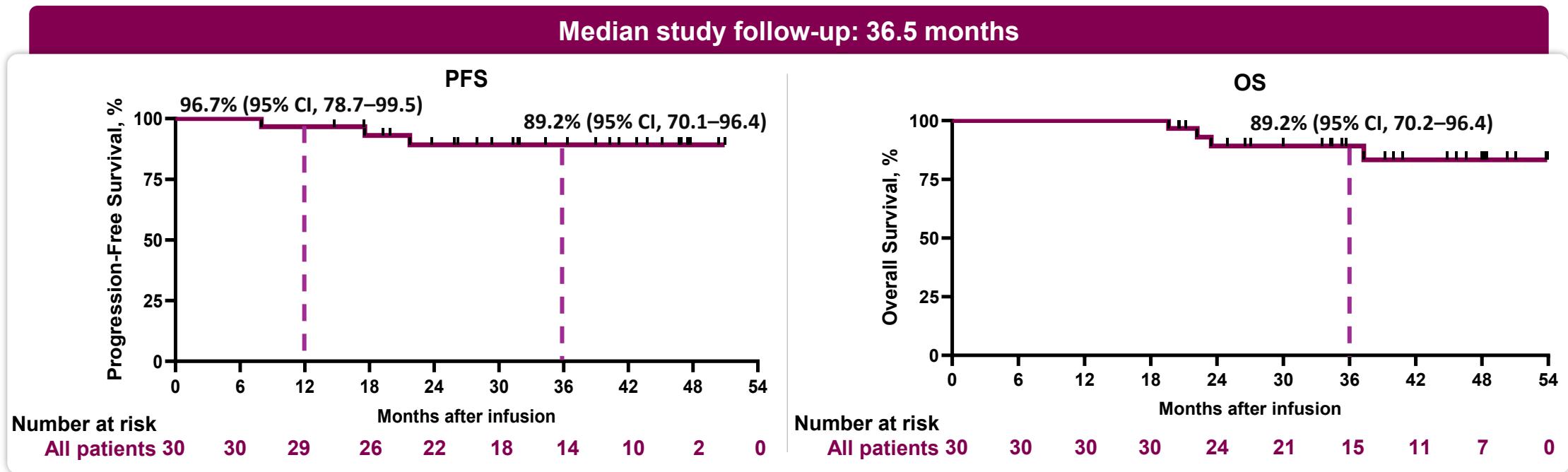
HR, high risk; NDMM, newly diagnosed multiple myeloma; ORR, overall response rate; sCR, stringent complete response; TE, transplant eligible; TI, transplant ineligible; VGPR, very good partial response.

Juan Du, MD, PhD

67th ASH Annual Meeting
December 6–9, 2025



Efficacy profile: PFS & OS



- No patients died within 12 months of AZD0120 infusion
- 23 patients (77%) received lenalidomide maintenance (median time to initiation was 6 months post infusion)
 - Two patients progressed and then died
- 7 patients did not receive lenalidomide maintenance, 5 of them remain in disease-free survival.
 - One experienced PD and subsequently died
 - One died without documented PD

OS, overall survival; PD, progressive disease; PFS, progression-free survival.

Juan Du, MD, PhD

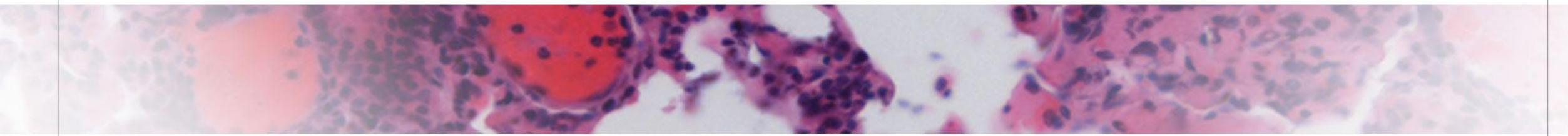
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A Phase 2 Trial of Abbreviated Fixed-Duration (Default 4 Cycles) Linvoseltamab Immuno-Consolidation to Deepen Responses Post Newly Diagnosed Multiple Myeloma Combination Therapy for Minimal Residual Disease Positivity (NCT06376526): The **IMMUNOPLANT™** Study

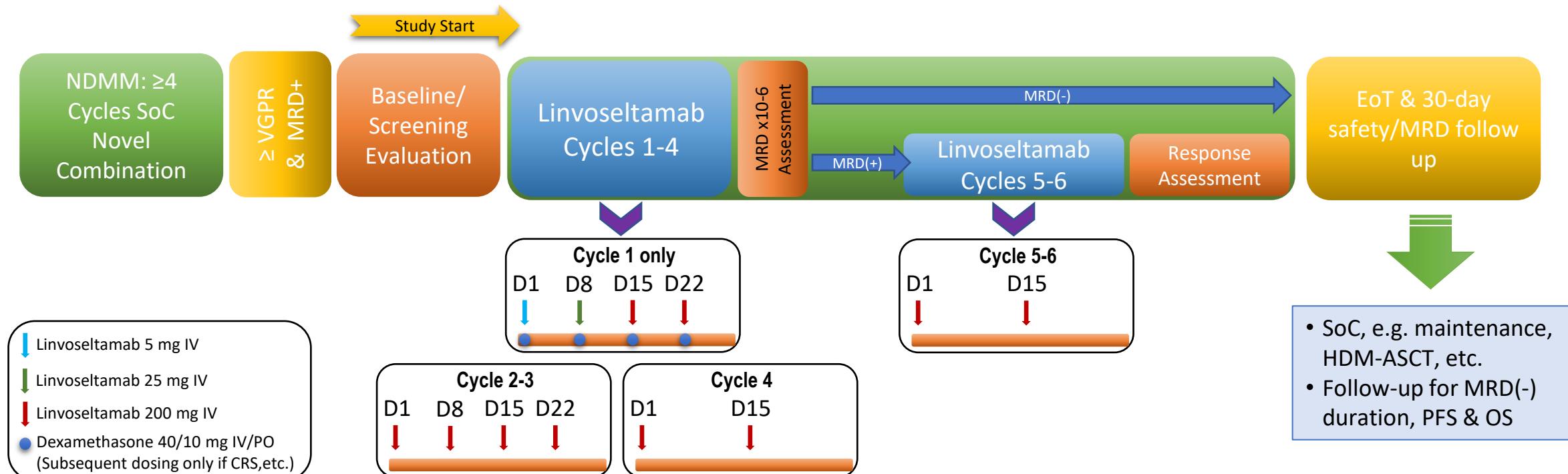
Dickran Kazandjian*, Benjamin Diamond, James Hoffman, Abhishek Pandey, David Coffey, Marcella Kaddoura, Brian Walker, David Lessen, Yaharini, Rodriguez, Caterine Diaz, Stephanie Mompoint, Sindy Gutierrez, Jennifer Chapman, Yi Zhou, Mike Georgiou, Russ Kuker, Kellye Koubek, Andrew Kowalski, Leslie Gallardo, Stephanie Fernandes, Fiorela Flores, Rabia Bukhari, Sunwoo Han, Michelle Armogan,

Ola Landgren

*Email: dkazandjian@miami.edu

Study Design: Schema

Immuno-consolidation for newly diagnosed **Multiple Myeloma** Using lack of MRD Negativity after initial cOmbination therapy to Pursue deeper responses with **Linvoseltamab ANd delay Transplant:**
The Phase 2 **IMMUNOPLANT™ Study**)



Key Eligibility

- PI/IMiD/anti-CD38 triplet/quad
- ≥4 cycles with MRD+ ≥VGPR
- adequate organ function

Statistical Hypothesis:

- Simon Minimax 2-Stage Design: Target MRD(-) Rate: 30%; null MRD(-) Rate: 10%
- Stage I: ≥2 of 15 patients with response--> continue enrollment
- Stage II: total ≥6 of 25 patients with response→ reject null hypothesis
- One sided alpha = 0.05; Power = 80%

Endpoints:

- Primary: MRD- 10^{-6} conversion rate
- Secondary: Safety, sustained MRD negativity, PFS, OS



American Society of Hematology

SYLVESTER
COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

MYELOMA
INSTITUTE

Brief Takeaways on Frontline Therapy

1. Single agent daratumumab is a legitimate option in high-risk smoldering myeloma using the 20/2/20 criteria
2. Quadruplets remain the standard of care in frontline MM with sustained responses
3. Teclistamab can be feasibly and effectively given in frontline myeloma in combination with daratumumab, even in the frail population
4. CAR T cell therapy frontline-in this case, dual targeting, is still early in development but with remarkable efficacy and safety
5. Novel approaches to achieve MRD negativity include adding fixed duration bispecific antibody therapy post induction

Early Relapse

1. Teclistamab-Dara in early relapse (LBA-6)
2. Long term follow up cilda-cel (#94)
3. Enhancing safety of cilda-cel (#1034)
4. Elranatamab plus Iberdomide (#100)
5. Functional High-Risk Definition (#1037)

Phase 3 Randomized Study of Teclistamab Plus Daratumumab Versus Investigator's Choice of Daratumumab and Dexamethasone With Either Pomalidomide or Bortezomib (DPd/DVd) in Patients With Relapsed Refractory Multiple Myeloma (RRMM): Results of MajesTEC-3

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MajesTEC-3: Phase 3 Study Design

Key inclusion criteria

- RRMM
- 1-3 prior LOTs including a PI and lenalidomide
 - Patients with only 1 prior LOT must have been lenalidomide refractory per IMWG criteria
- ECOG PS score of 0-2

Key exclusion criteria

- Prior BCMA-directed therapy
- Refractory to anti-CD38 mAbs^a

1:1
randomization
N=587
22 Oct 2021 to
29 Sept 2023^b

Tec-Dara
N=291
SC dosing following Dara schedule

DPd/DVd
N=296 (91% DPd)
by investigator's choice^c

Primary endpoint

- PFS per IRC

Key secondary endpoints

- ≥CR^d and ORR^d
- MRD negativity (10^{-5})
- OS
- MySIm-Q Total Symptom score

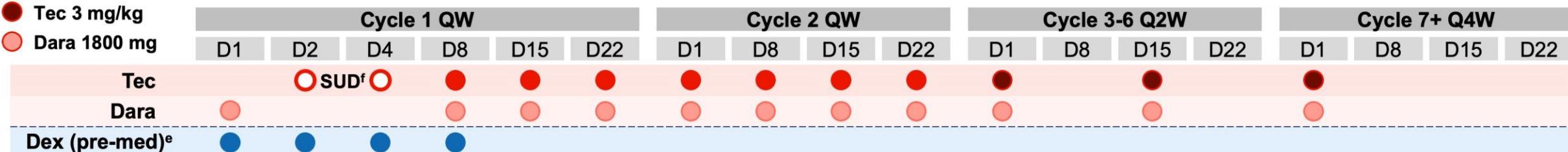
Other secondary endpoints

- Safety
- PK and immunogenicity

● Tec 1.5 mg/kg

● Tec 3 mg/kg

● Dara 1800 mg



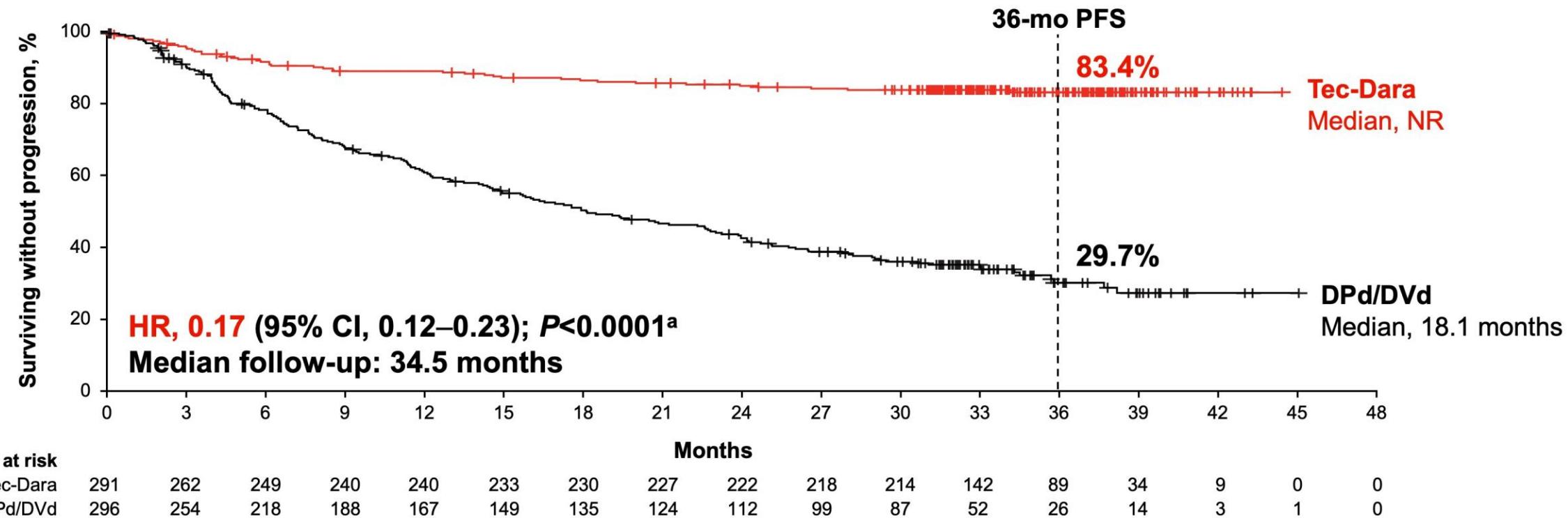
**SC dosing aligned with Dara schedule, with monthly dosing after 6 cycles;
steroid sparing after Cycle 1 Day 8**

^aPrior exposure to anti-CD38 mAbs was permitted. ^bDuring the COVID-19 pandemic. ^cDPd/DVd were administered per the approved schedules. ^dResponse and disease progression were assessed by a blinded IRC per IMWG criteria. ^eDexamethasone, acetaminophen, and diphenhydramine pre-medication was required for the first 2 weeks; subsequent dexamethasone was not required thereafter. ^fPatients received SUD of 0.06 mg/kg and 0.3 mg/kg on Days 2 and 4, respectively.

CR, complete response; D, day; Dex, dexamethasone; DPd, daratumumab, pomalidomide, and dexamethasone; DVd, daratumumab, bortezomib, and dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; IRC, independent review committee; MRD, minimal residual disease; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; ORR, overall response rate; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; pre-med, pre-medication; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; SC, subcutaneous; SUD, step-up dosing.



MajesTEC-3: PFS (Primary Endpoint)



Tec-Dara significantly improved PFS, with a plateauing curve after ~6 months and >90% of patients progression-free at 6 months sustaining such a benefit at 3 years

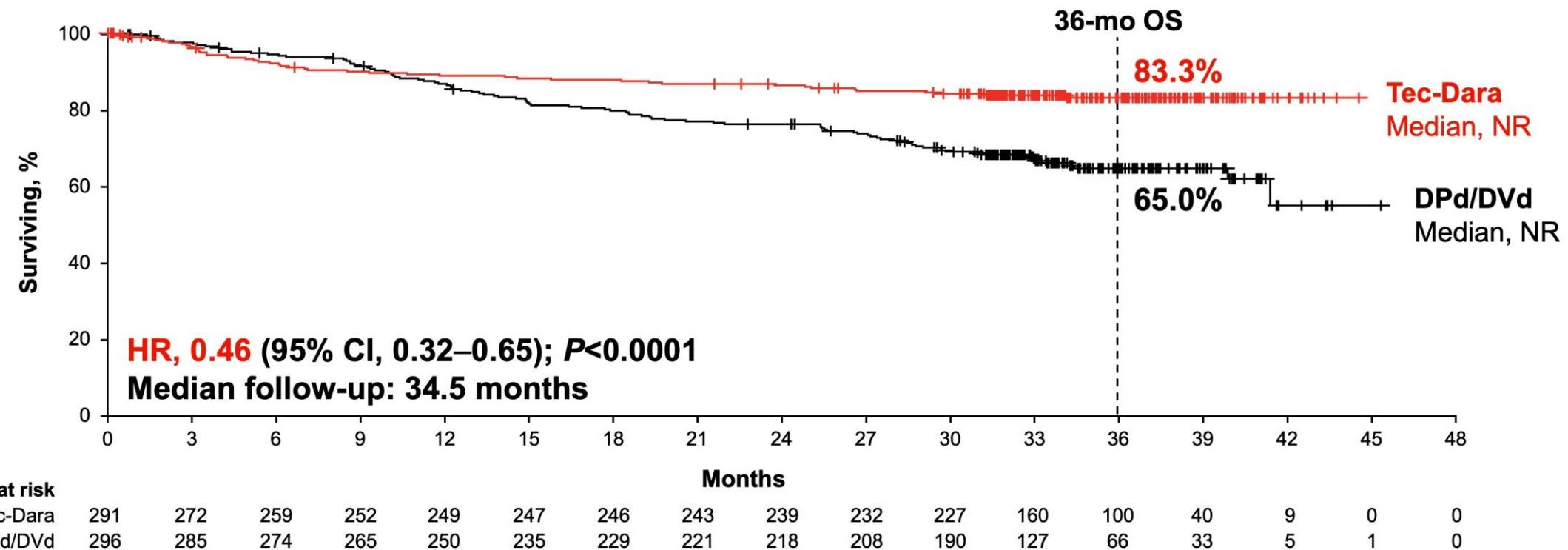
^aThe P value crossed the prespecified stopping boundary for superiority for the first interim analysis ($P=0.0139$).

CI, confidence interval; HR, hazard ratio; NR, not reached.

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MajesTEC-3: OS



Tec-Dara significantly improved OS versus DPd/DVd, with 83% of patients alive at 3 years

Analysis of RMST demonstrated an OS benefit for Tec-Dara versus DPd/DVd (RMST difference, 2.15 months; $P=0.0088$).

RMST, restricted mean survival time.

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MajesTEC-3: Summary of Infections

- Study started during the COVID-19 pandemic and prior to bispecific treatment guidelines
- Hypogammaglobulinemia^a: 84.5% with Tec-Dara
- 13 (4.6%) deaths due to infection with Tec-Dara^b
 - 12 occurred within 6 months of treatment (3 due to COVID-19); 9 of 12 patients did not receive IgRT
 - Protocol was subsequently amended in Feb 2023 to reinforce IgRT supplementation and antimicrobial prophylaxis^c
 - 87.3% received ≥ 1 dose of Ig^d
 - 1 infectious death occurred post amendment

TEAE, n (%)	Tec-Dara (n=283)		DPd/DVd (n=290)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Any infection	273 (96.5)	153 (54.1)	244 (84.1)	126 (43.4)
Treatment-emergent infection or infestation ^e				
COVID-19	124 (43.8)	17 (6.0)	97 (33.4)	6 (2.1)
URTI	115 (40.6)	12 (4.2)	88 (30.3)	7 (2.4)
Pneumonia	65 (23.0)	47 (16.6)	53 (18.3)	43 (14.8)
Nasopharyngitis	62 (21.9)	0	57 (19.7)	0
Sinusitis	52 (18.4)	5 (1.8)	17 (5.9)	3 (1.0)
Rhinovirus infection	44 (15.5)	5 (1.8)	10 (3.4)	1 (0.3)
Bronchitis	40 (14.1)	2 (0.7)	31 (10.7)	6 (2.1)
Influenza	38 (13.4)	8 (2.8)	43 (14.8)	10 (3.4)
COVID-19 pneumonia	34 (12.0)	32 (11.3)	12 (4.1)	7 (2.4)
UTI	29 (10.2)	4 (1.4)	27 (9.3)	1 (0.3)

Infections with Tec-Dara require diligent use of established IgRT and prophylaxis protocols

^aHypogammaglobulinemia was defined as patients with ≥ 1 TEAE of hypogammaglobulinemia or a post-baseline IgG value <400 mg/dL. Rate of hypogammaglobulinemia in the DPd/DVd arm was 60.3%. ^bIn the DPd/DVd group, 4 patients had a fatal infection, 2 of which occurred after the implementation of protocol amendment #6. ^cProtocol amendment #6 affirmed the importance of medical monitoring of IgG levels and adherence to protocol-specified IgG supplementation guidance. ^dPercentage at clinical cutoff. ^eMost common defined as occurring in $\geq 10\%$ of patients in either treatment group; shown with percent occurrence of respective grade 3/4 infection.

Ig, immunoglobulin; IgG, immunoglobulin G; IgRT, immunoglobulin replacement therapy; UTI, urinary tract infection.

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Long-Term Progression-Free Survival Benefit With Ciltacabtagene Autoleucel in Standard-Risk Relapsed/Refractory Multiple Myeloma

Luciano Costa¹, Albert Oriol², Dominik Dytfield³, Salomon Manier⁴, Peter Voorhees⁵, Yi Lin⁶, Myo Htut⁷, Wilfried Roeloffzen⁸, Phoebe Joy Ho⁹, Urvi Shah¹⁰, Man Zhao¹¹, Quanlin Li¹², Agnes Balogh¹³, Katherine Li¹⁴, Ana Slaughter¹⁵, Nina Benachour¹³, Carolina Lonardi¹⁶, Arnab Ghosh¹⁷, Huabin Sun¹⁷, Nikoletta Lendvai¹⁷, Tamar Lengil¹⁷, Nitin Patel¹⁸, Mythili Koneru¹⁸, Erika Florendo¹⁸, Octavio Costa¹⁸, Vrinda Mahajan¹⁸, Paula Rodríguez-Otero¹⁹, Christopher Strouse²⁰, A. Keith Stewart²¹, Surbhi Sidana²²

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³Poznan University of Medical Sciences, Poznań, Poland; ⁴University of Lille, CHU Lille, Lille, France; ⁵Atrium Health/Levine Cancer Institute, Wake Forest University School of Medicine, Charlotte, NC, United States; ⁶Mayo Clinic, Rochester, MN, United States; ⁷Department of Hematology and Hematopoietic Cell Transplantation, City of Hope Comprehensive Cancer Center, Duarte, CA, United States; ⁸Department of Hematology, University Medical Center Groningen, Groningen, Netherlands; ⁹Royal Prince Alfred Hospital, Sydney, Australia; ¹⁰Myeloma Service, Memorial Sloan Kettering Cancer Center, and Weill Cornell Medical College, New York, NY, United States; ¹¹IQVIA, Shanghai, China; ¹²Johnson & Johnson, Apex, NC, United States;

¹³Johnson & Johnson, Beerse, Belgium; ¹⁴Johnson & Johnson, Spring House, PA, United States; ¹⁵Johnson & Johnson, Zug, Switzerland; ¹⁶Johnson & Johnson, Buenos Aires, Argentina;

¹⁷Johnson & Johnson, Raritan, NJ, United States; ¹⁸Legend Biotech USA Inc, Somerset, NJ, United States; ¹⁹Cancer Center Clínica Universidad de Navarra, Cima, Pamplona, Spain;

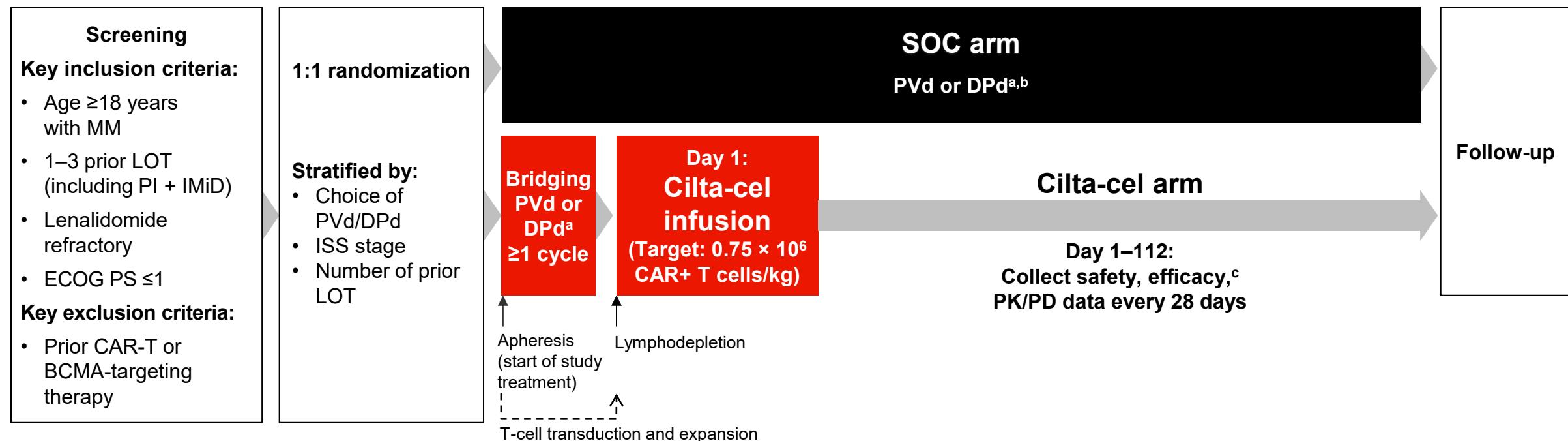
²⁰Hematology, Oncology, and Blood & Marrow Transplantation, University of Iowa, Iowa City, IA, United States; ²¹University Health Network and the Princess Margaret Cancer Centre, Toronto, ON, Canada; ²²Stanford University School of Medicine, Stanford, CA, United States

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CARTITUDE-4: Study Design¹



Primary endpoint

- PFS^d

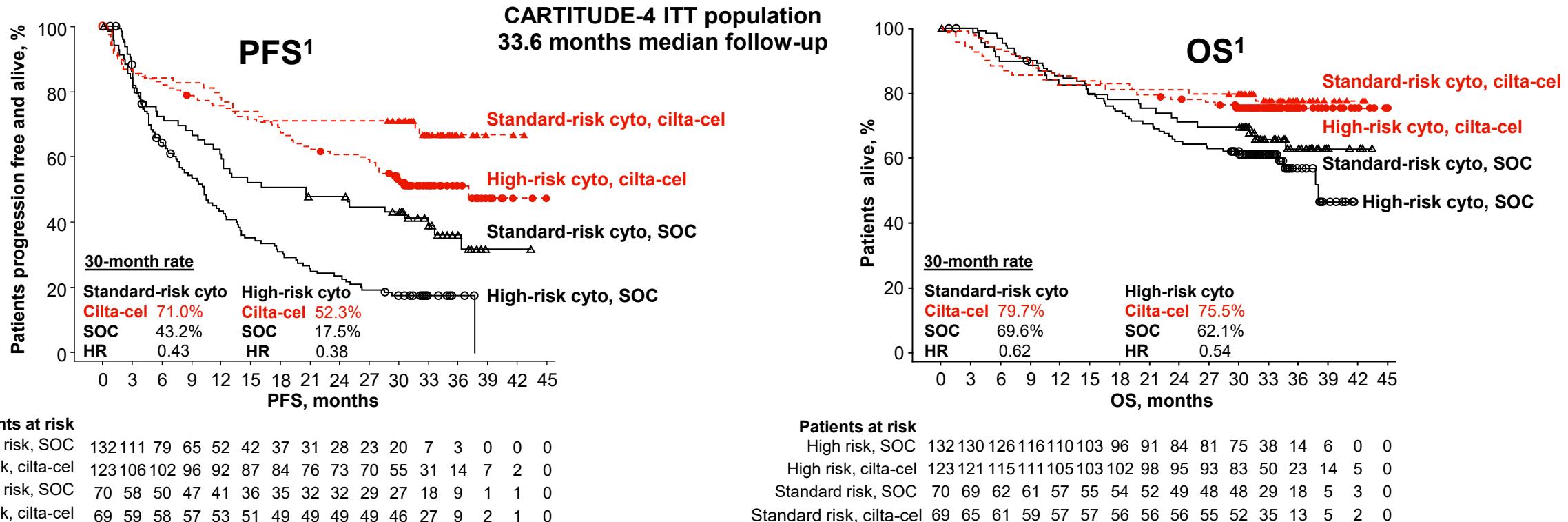
Secondary endpoints

- Efficacy: \geq CR, ORR, MRD negativity, OS
- Incidence and severity of AEs

^aPhysician's choice. ^bAdministered until disease progression. ^cEfficacy data were collected after Day 112 every 28 days. ^dTime from randomization to disease progression/death. AE, adverse event; BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CTCAE, Common Terminology Criteria for Adverse Events; DPd, daratumumab, pomalidomide, and dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IMiD, immunomodulatory drug; ISS, International Staging System; ORR, overall response rate; PD, pharmacodynamics; PI, proteasome inhibitor; PK, pharmacokinetics; PVd, pomalidomide, bortezomib, and dexamethasone. 1. San-Miguel J, et al. *N Engl J Med* 2023;389:335–47.



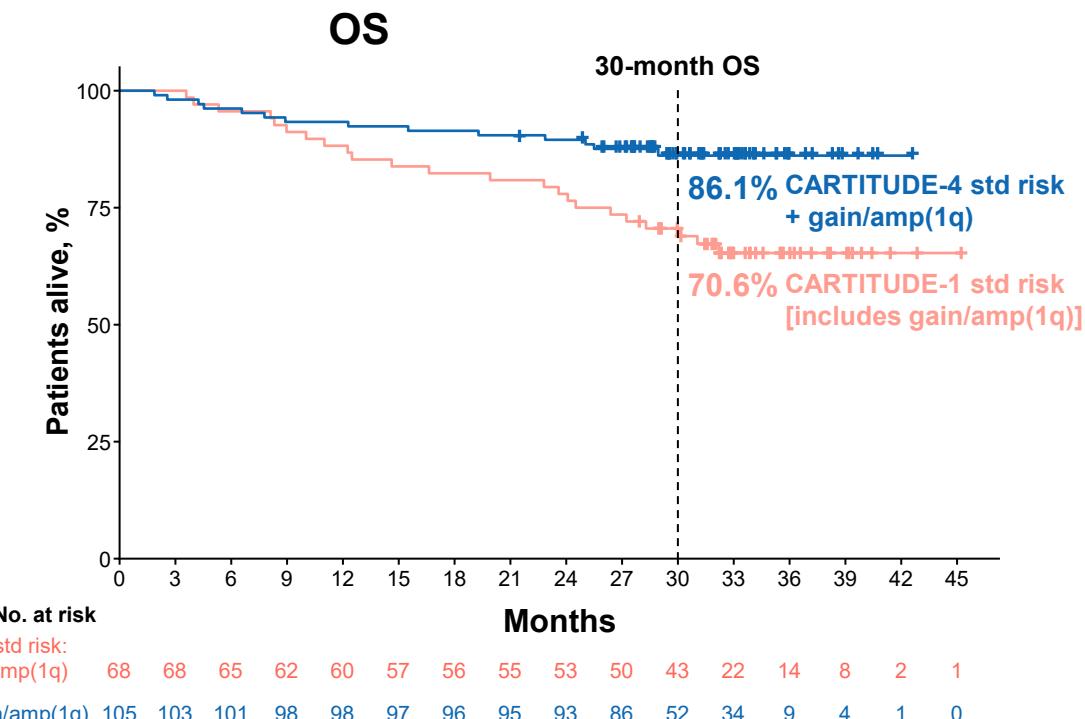
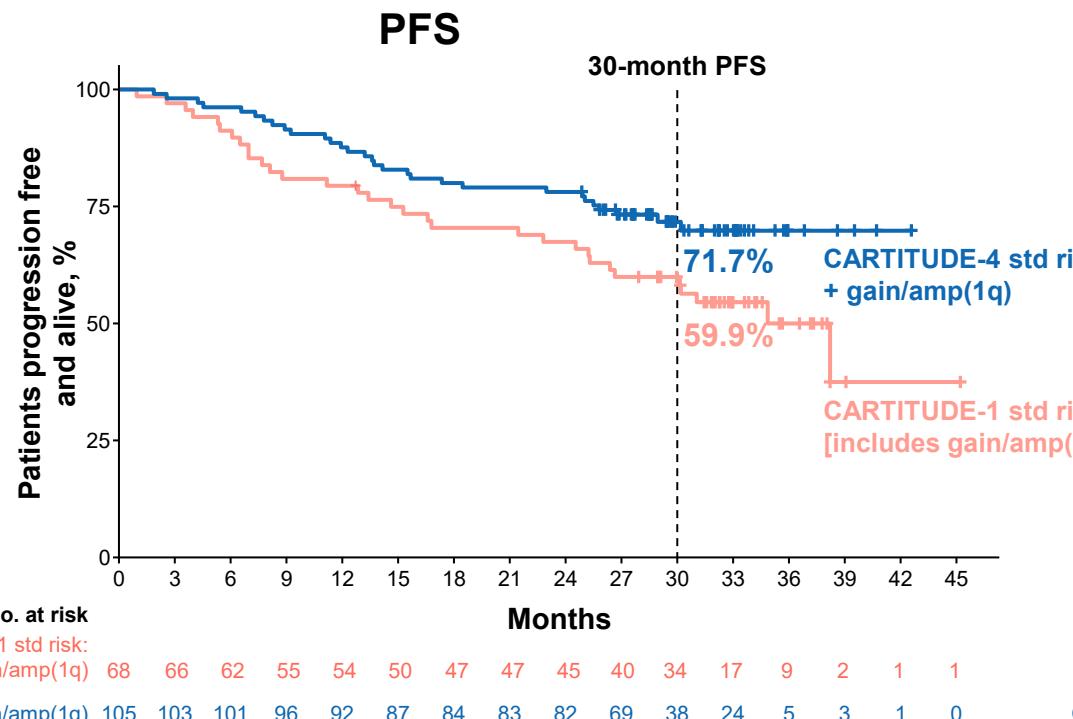
PFS and OS in Patients With High-Risk and Standard-Risk Cytogenetics (ITT)



In CARTITUDE-4, cilta-cel improved PFS and OS in prespecified subgroups with standard- and high-risk cytogenetics¹

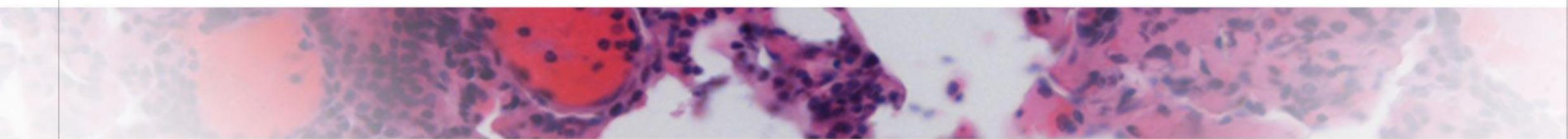


CARTITUDE-4 and CARTITUDE-1: PFS and OS in Patients With Standard-Risk Cytogenetics (As-Treated)



Survival rates were higher when ciltacel was used earlier in standard-risk disease



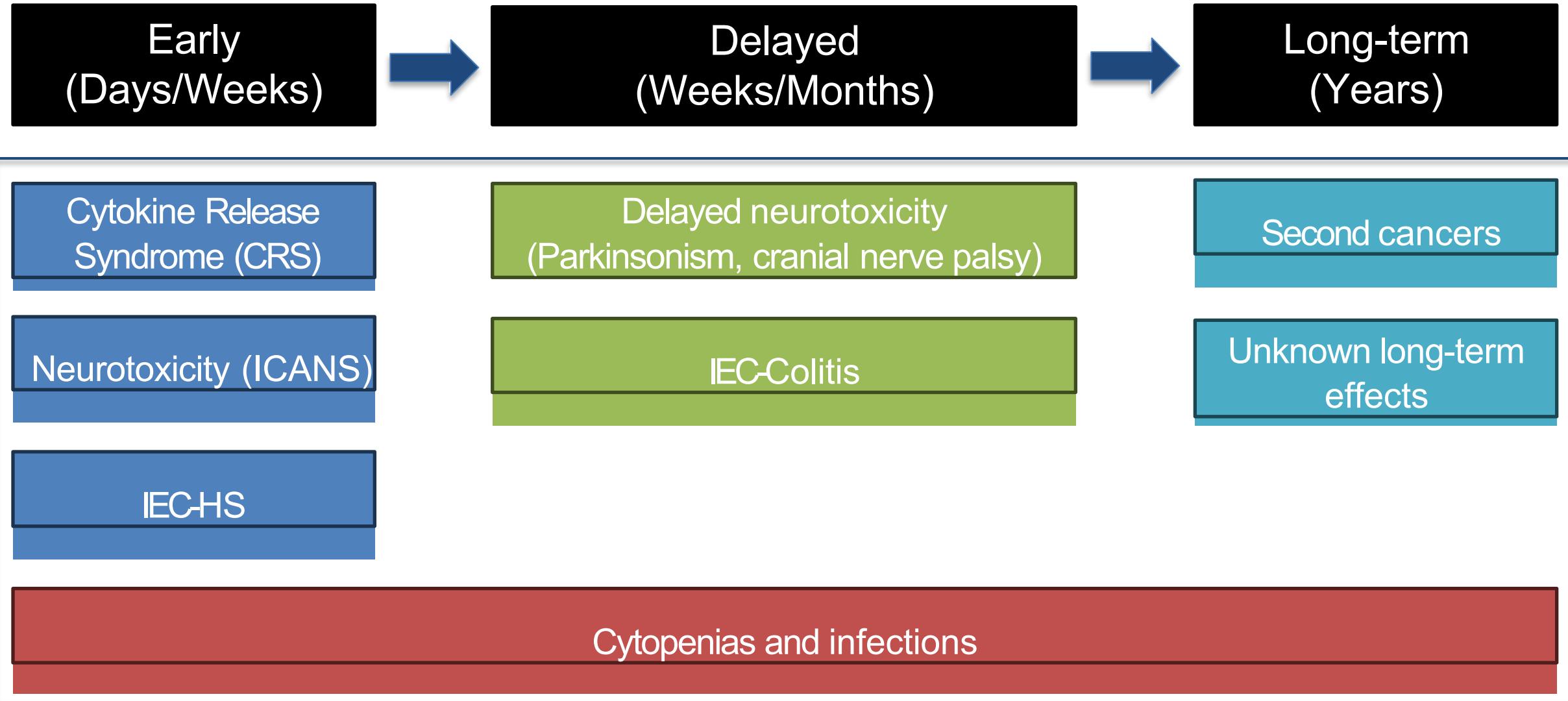


Enhancing the safety of ciltacabtagene autoleucel in relapsed multiple myeloma (MM): Identification of potentially modifiable risk-factors associated with delayed neurotoxicity and non-relapse mortality

Surbhi Sidana*, Brett Reid*, Danai Dima*, Lauren C. Peres, Mahmoud Gaballa, Rahul Banerjee, Oren Pasvolsky, Aimaz Afrough, Christen Dillard, Christopher Ferreri, Shebli Atrash, Cindy Varga, Andrew Portuguese, Masooma Rana, Hitomi Hosoya, Lekha Mikkilineni, Vanna Hovanky, Saurabh Zanwar, Nilesh Kalariya, Damian Mikulski, Charlotte Wagner, Christopher R. Cahoon, Omar Castaneda Puglianini, Gabe De Avila, Christian Gordillo, Eli Zolotov, Jenny Bhurtel, Ariel Grajales-Cruz, Utkarsh Goel, Aishwarya Sannareddy, Jeries Kort, Rafaella Cassano, Shonali Midha, James Davis, Rebecca Gonzalez, Megan Herr, Zhuoer Xie, Hamza Hassan, Sneha Purvey, Marcus Geer, Kimberly Green, Fabiana Perna, Hien Liu, Taiga Nishihori, Jack Khouri, Shahzad Raza, Faiz Anwer, Susan Bal, Omar Nadeem, Ciara L. Freeman, Leyla Shune, Ran Reshef, Kenneth Shain, Melissa Alsina, Rachid Baz, Doug Sborov, Saurabh Dahiya, Frederick L. Locke, David Miklos, Peter Voorhees, Larry Anderson, Luciano Costa, Noa Biran, Shaji Kumar, Yi Lin*, Krina K. Patel*, Doris Hansen*

* contributed equally

Toxicities with Cilta-cel



Study Design

Population

- Patients with relapsed MM receiving standard of care ciltacel
- Sites: 15 U.S centers
- **N=761** (May 2022 to December 2024)

Definitions

- **Delayed neurotoxicity (DNT) or Non-ICANS neurotoxicity (NINT):** Neurotoxicity events except ICANS including Parkinsonism, cranial nerve palsy, neuropathy, etc
- **NRM** was defined as death due any cause except myeloma progression

Analysis

- Risk factors for Parkinsonism and NRM were evaluated by univariable and multivariable analysis.
- Any NRM events occurring after disease progression were censored for analysis, except second primary malignancies

Summary

- Non-response to bridging therapy was associated with 10x risk of Parkinsonism and a higher NRM with ciltacel
- **Effective tumor debulking with bridging is critical to decrease the risk of Parkinsonism and NRM with ciltacel**
- Peak ALC was significantly higher in patients who developed Parkinsonism, with peak $\geq 3000/\mu\text{L}$ associated with 12% risk of Parkinsonism.
- Peak ALC $\geq 3000/\mu\text{L}$ can serve as a biomarker to identify patients for preemptive interventions and risk mitigation measures

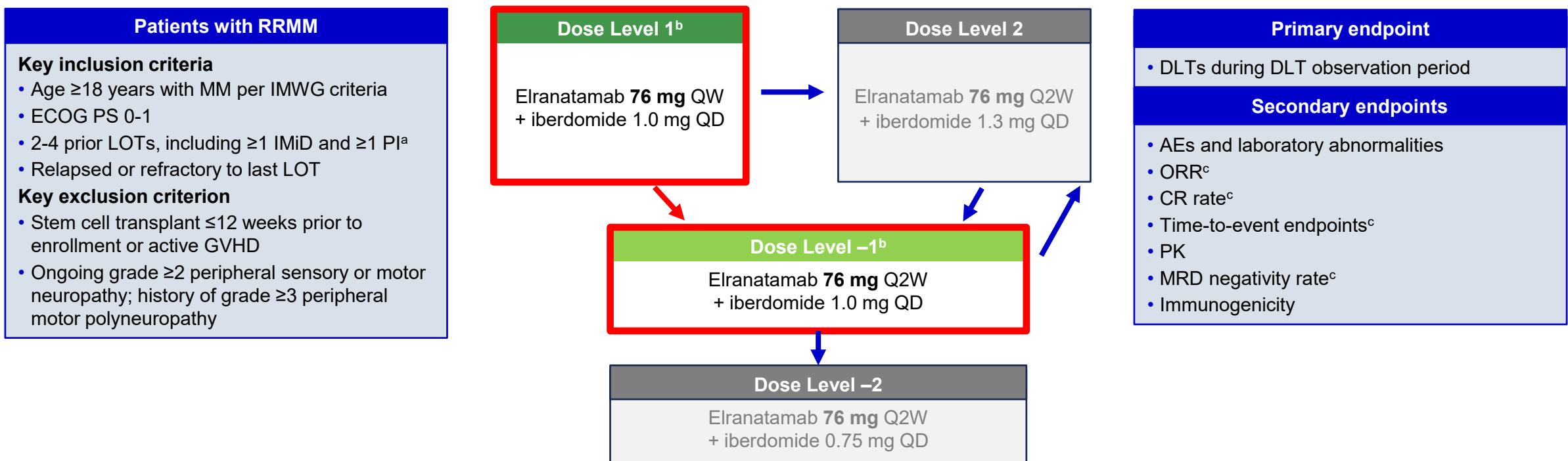
Safety and Efficacy of Elranatamab in Combination With Iberdomide in Patients With Relapsed or Refractory Multiple Myeloma: Results from the Phase 1b MagnetisMM-30 Trial

Attaya Suvannasankha,¹ Jonathan L. Kaufman,² Ashraf Badros,³ Michel Pavic,⁴ Hock-Choong Lai,⁵ Muhammad S Raza,⁶ Parth S Shah,⁷ Patrick Y. Muller,⁸ Jorge Acosta,⁸ Margaret Hoyle,⁹ Erik R Vandendries,¹⁰ Jay Cheng,¹¹ Alexander Lesokhin¹²

¹*Melvin and Bren Simon Comprehensive Cancer Center, Indiana University, Indianapolis, IN, USA;* ²*Winship Cancer Institute, Emory University, Atlanta, GA, USA;* ³*Greenebaum Comprehensive Cancer Center, University of Maryland, Baltimore, MD, USA;* ⁴*Centre Intégré Universitaire de Santé et de Services Sociaux de l'Estrie - Centre Hospitalier Universitaire de Sherbrooke, Quebec, QC, Canada;* ⁵*Icon Cancer Centre Townsville, Queensland, AU;* ⁶*Dr. Everett Chalmers Hospital, Halifax, NS, Canada;* ⁷*Dartmouth Hitchcock Medical Center, Hanover, NH, USA;* ⁸*Bristol Myers Squibb, Boudry, Switzerland;* ⁹*Pfizer Inc, Milan, Italy;* ¹⁰*Pfizer Inc, Cambridge, MA, USA;* ¹¹*Pfizer Inc, Bothell, WA, USA;* ¹²*Memorial Sloan Kettering Cancer Center, New York, NY, USA*

MagnetisMM-30 Study Design

- MagnetisMM-30 (NCT06215118) is a phase 1b, open-label, multicenter, prospective study
- **Part 1** (dose escalation) primary objective was to assess the tolerability and safety of elranatamab in combination with iberdomide to determine the recommended doses of the combination for evaluation in **Part 2** (randomized dose optimization)
 - A BOIN approach was used to guide dose escalation/de-escalation in **Part 1**

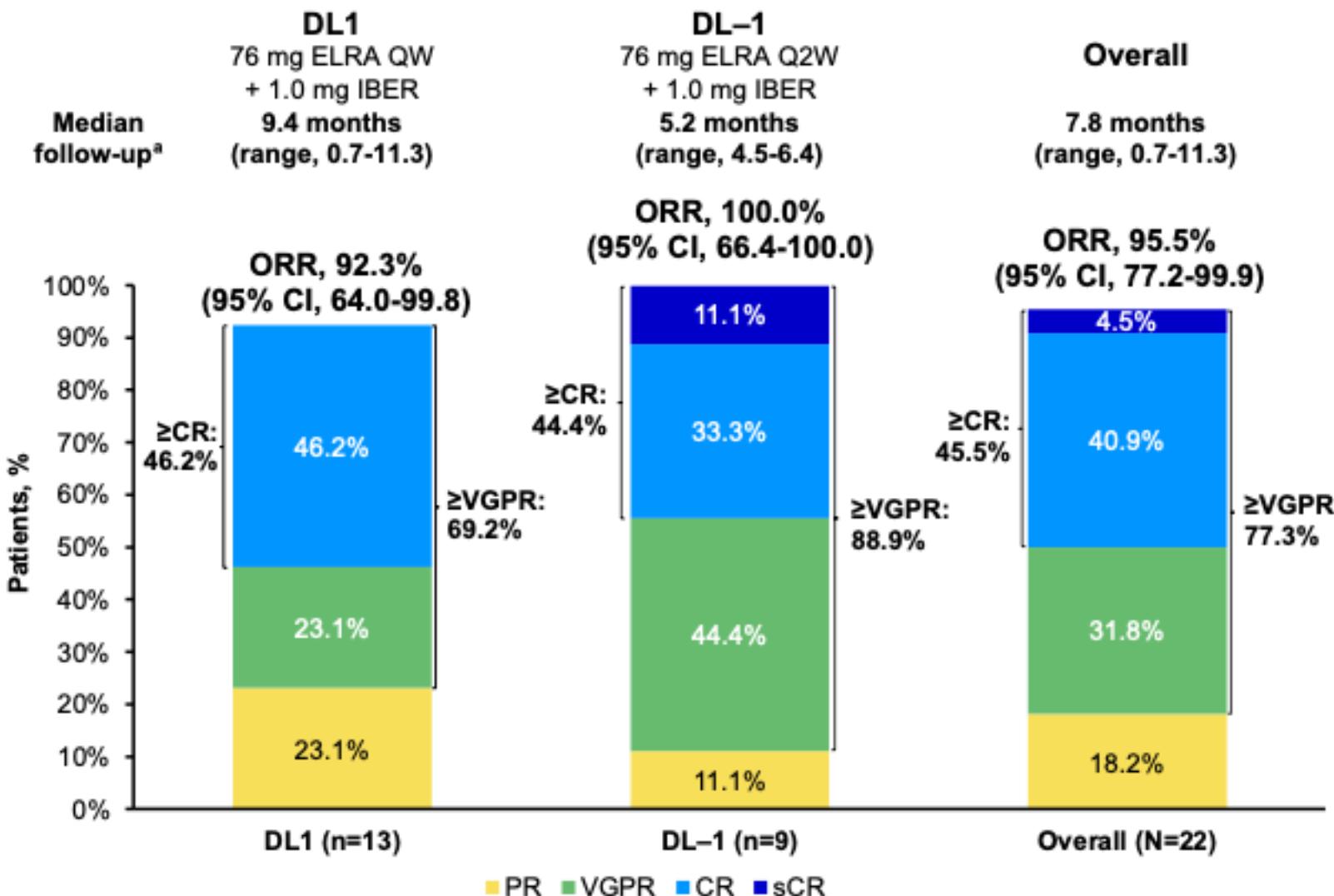


^a All patients must have received ≥ 2 consecutive cycles of an IMiD-containing regimen and ≥ 2 consecutive cycles of a PI or PI-containing regimen; ^b All patients received an initial 14-day cycle of elranatamab (12 mg on day 1, 32 mg on day 4, 76 mg on day 8) without iberdomide. Iberdomide was dosed at 21 out of 28 days for subsequent cycles; ^c Per IMWG criteria

AE=adverse event; BOIN=Bayesian Optimal Interval Design; CR rate=complete response rate; DLT=dose-limiting toxicity; ECOG PS=Eastern Cooperative Oncology Group performance status; GVHD=graft vs host disease; IMiD=immunomodulatory drug; IMWG=International Myeloma Working Group; LOT=line of therapy; MM=multiple myeloma; MRD=minimal residual disease; ORR=objective response rate; PI=proteasome inhibitor; PK=pharmacokinetics; QD=once daily; QW=once weekly; Q2W=once every 2 weeks

ORR

- Overall, the confirmed ORR by investigator was 95.5% (95% CI, 77.2-99.9)
- Responses occurred early
 - Median time to response was 1.4 months (range, 0.5-2.7)



^a Simple median of observation times.

CR=complete response; DL=dose level; ELRA=elranatamab; IBER=berdomide; ORR=objective response rate; PR=partial response; sCR=stringent complete response; VGPR=very good partial response

Redefining Functional High-Risk (FHR) Multiple Myeloma (MM) in the Context of Upfront Quadruplet (QUAD) Therapy and Autologous Stem Cell Transplantation (ASCT)

Luciano Costa¹, Susan Bal¹, Kelly Godby¹, Gayathri Ravi¹, Eva Medvedova², Natalie Callander³, Rebecca Silbermann², Bhagi Dholaria⁴, Forest Huls⁵, Baylie Mullinax¹, Laura Joiner¹, Caitlin Hagedorn¹, Binod Dhakal⁶.

1 University of Alabama at Birmingham, Division of Hematology and Oncology, Birmingham, AL; 2 Oregon Health Sciences University, Portland, OR; 3 University of Wisconsin, Madison, WI, United States; 4 Vanderbilt University, Nashville, TN; 5 University of Alabama at Birmingham, Department of Pathology, Birmingham, AL; 6 Medical College of Wisconsin, Milwaukee, WI.



Conclusions

In NDMM treated with QUAD + ASCT :

FHR36 identifies a population with expected OS ~24 months= New Definition

FHR36 is associated with worse response, 2PFS and OS in patients with progression after QUAD + ASCT

TCRT in 2nd line is associated with improved 2PFS in patients with progression after QUAD + ASCT

Brief Takeaways on Early Relapse

1. The combination of Teclistamab and Daratumumab in early relapse is remarkable and will likely be available soon - but infectious concerns must be mitigated
2. Long term outcomes with ciltacel in standard risk are excellent with 30-month PFS 80% in early line and 60% in late line
3. Key toxicities with ciltacel can be mitigated with bridging therapy and ALC monitoring
4. Combining Elranatamab and Iberdomide is both feasible and effective
5. The definition of Functional High Risk could reset to 36 months due to better outcomes in frontline therapy

Late Relapse

1. *in vivo* CAR T (LBA-1)
2. Anito-cel in relapsed MM (#256)
3. AZD0120 CAR T (#269)
4. Teclistamab-Talquetamab in EMD (#698)
5. Etentamig plus pomalidomide (#247)

LBA-1

**MRD-negative outcomes following a novel,
in vivo gene therapy generating anti-BCMA
CAR-T cells in patients with RRMM:
Preliminary results from inMMyCAR, the
first-in-human Phase 1 study of KLN-1010**

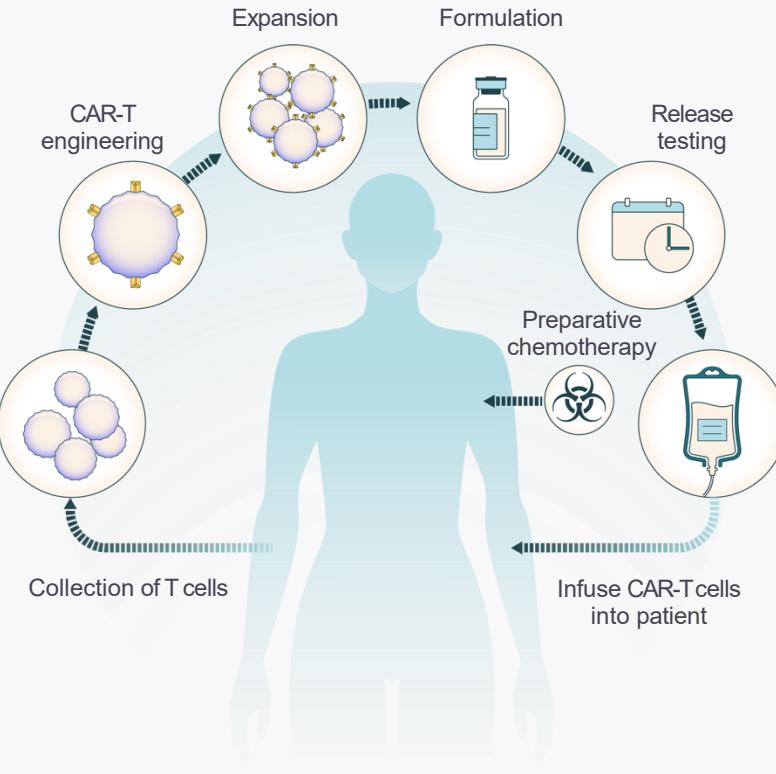
Simon Harrison¹, P. Joy Ho², Sueh-li Lim³, Stephanie Talam², Hannah Pahl¹,
Dharmesh Dingar⁴, Scott Currence⁴, Travis Quigley⁴, Andrew Spencer³

¹Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia; ²Royal Prince Alfred Hospital, Sydney, New South Wales, Australia; ³The Alfred Hospital, Melbourne, Victoria, Australia;
⁴Kelonia Therapeutics, Inc., Boston, Massachusetts, United States.

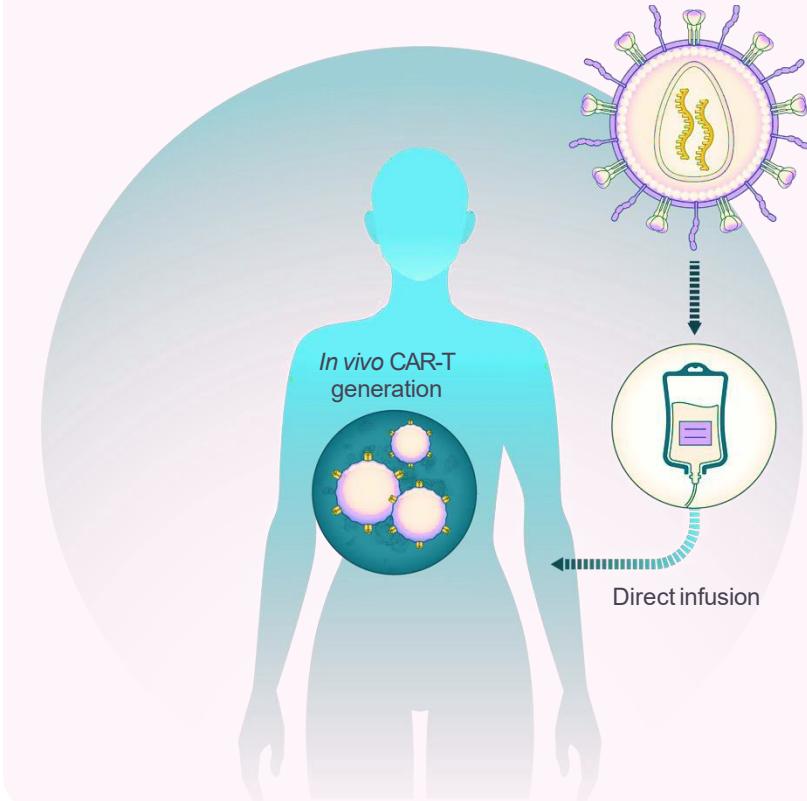


Expanding the reach of CAR-T cells with *in vivo* gene delivery^{1,2}

Ex vivo CAR T



In vivo CAR T with KLN-1010 lentiviral particles

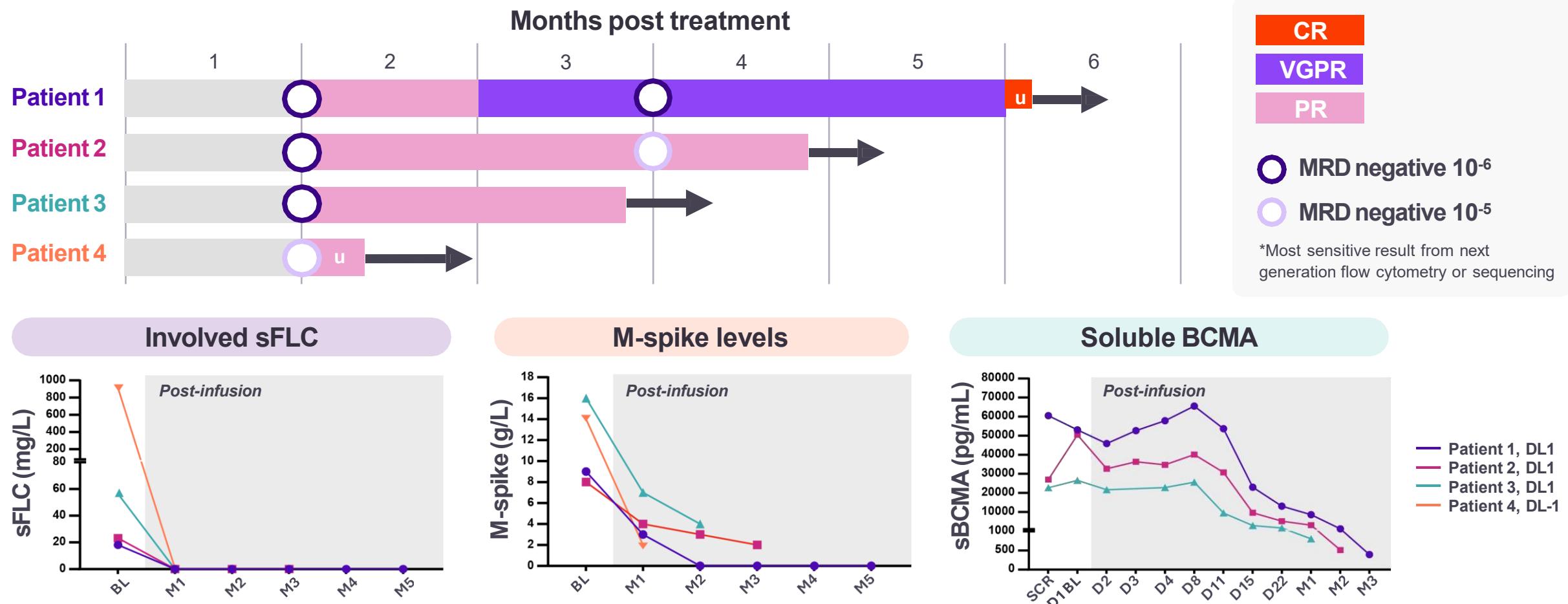


- Eliminates preconditioning lymphodepletion
- Greatly simplified logistics to expand access
- No ex vivo culture may increase T-cell fitness
- Reduced cost of goods and manufacturing

CAR, chimeric antigen receptor.

1. Bot A et al. *Nat Rev Drug Discov.* 2025 Sep 30. doi: 10.1038/s41573-025-01291-5; 2. Najibi AJ. T cell-specific *in vivo* transduction with preclinical candidate KLN-1010 generates BCMA-directed CAR-T cells with potent anti-multiple myeloma activity (abstract #48). Poster presented at: AACR Annual Meeting; April 5-10, 2024.

Deep, ongoing MRD-negative responses were observed across first 4 patients



BCMA, B-cell maturation antigen; BL, baseline; CR, complete response; D, study day; M, study month; M-spike, monoclonal protein spike; MRD, minimal residual disease; PR, partial response; SCR, screening; sFLC, serum free light chain; u, unconfirmed response; VGPR, very good partial response.

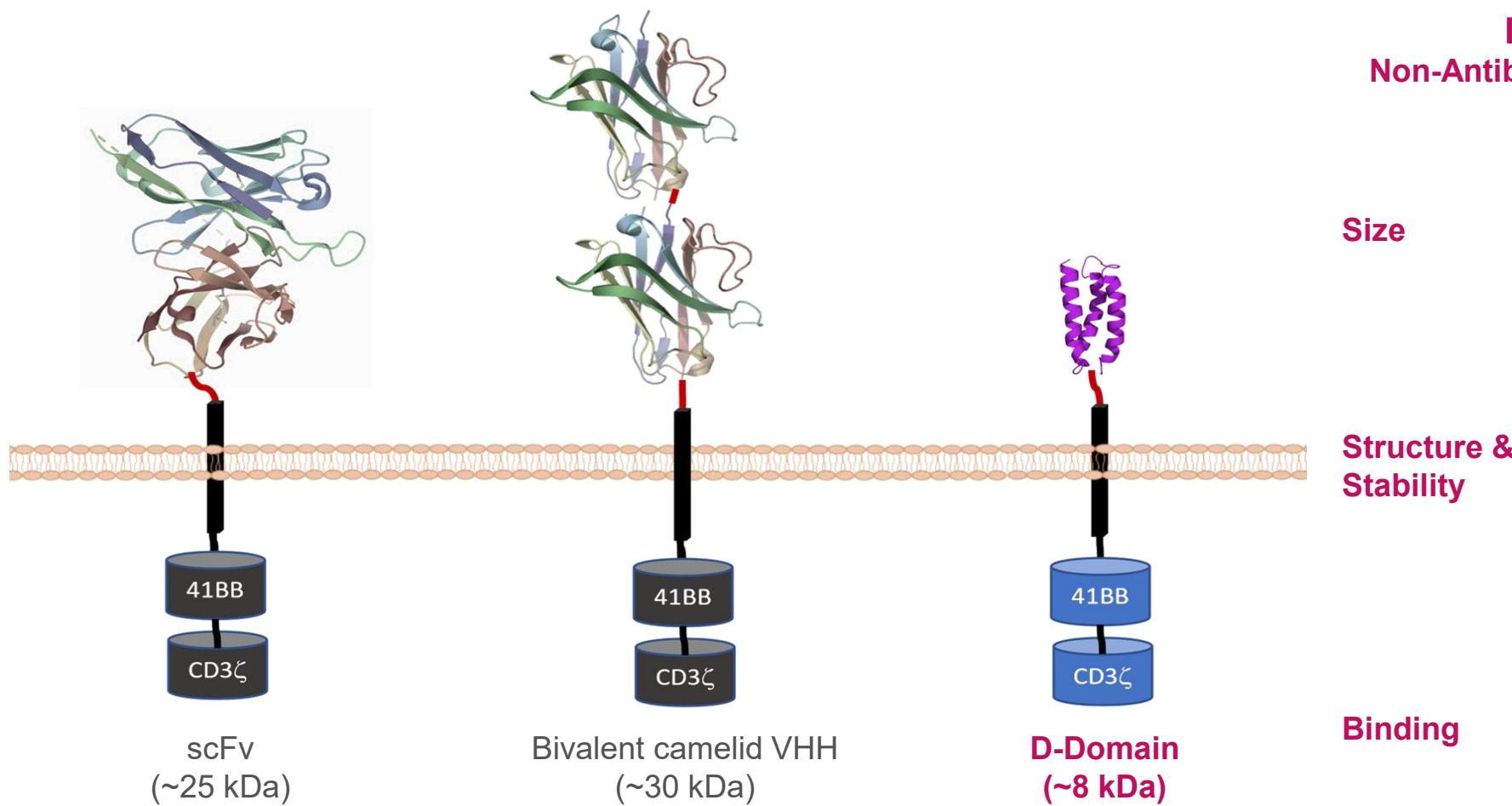
Abstract 256

Phase 2 Registrational Study of Anitocabtagene Autoleucel for the Treatment of Patients with Relapsed and/or Refractory Multiple Myeloma (RRMM): Updated Results from iMImagine-1

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Anitocabtagene autoleucel (anito-cel/CART-ddBCMA)

Autologous BCMA-directed CAR T-cell therapy using a novel, D-Domain binder^{1,2}



D-Domain Attributes: Non-Antibody Derived Synthetic Protein^{1,2}

Small D-Domain construct facilitates high transduction efficiency and CAR positivity²⁻⁴ resulting in a low total cell dose

Size

D-Domain CARs are stable and lack tonic signaling^{4,6} due to the rapid folding, lack of disulfide bonds, and hydrophobic core^{5,6} of the D-Domain

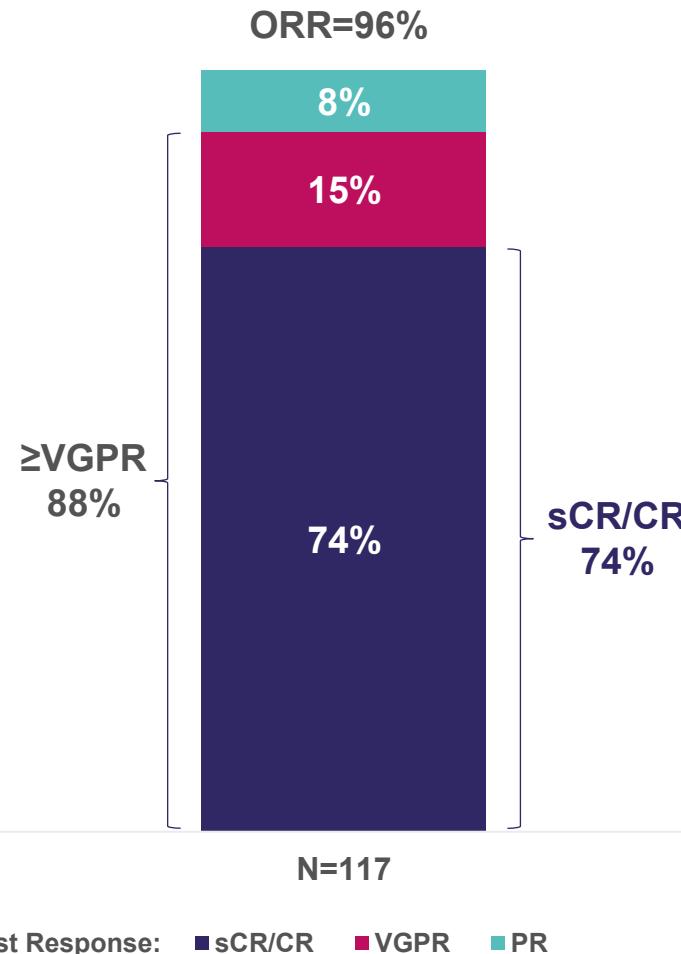
Structure & Stability

The D-Domain binder has a fast off-rate⁴ and high CAR surface expression⁴. This combination may allow optimal tumor cell killing without prolonged inflammation

¹Rotte, et al. *Immuno-Oncology Insights* 2022; 3(1), 13–24; ²Frigault, et al. *Blood Adv.* 2023; 7(5):768-777; ³Cante-Barrett, et al. *BMC Res. Notes* 2016; 9:13; ⁴Buonato, et al. *Mol. Cancer Ther.* 2022; 21(7):1171-1183; ⁵Zhu, et al. *Proc. Nat. Acad. Sci.* 2003; 100(26): 15486-15491; ⁶Qin, et al. *Mol. Ther.* 2019; 27(7): 1262-1274.

iMImagine-1: Overall Response Rate and Depth of Response

Efficacy Evaluable Patients, N=117



- Responses continue to deepen over time
- At a median follow-up of 15.9 months, IRC-assessed ORR was 96% and sCR/CR rate was 74%

	Median (months)	Interquartile Range	Min, Max
Time to first response	1.0	1.0, 1.9	0.9, 13.8
Time to best response	4.8	2.1, 9.0	0.9, 23.8
Time to sCR/CR	3.2	2.0, 9.2	0.9, 23.8

Responses are per IMWG criteria and are IRC assessed; ORR defined as partial response or better.
CR, complete response; IRC, independent review committee; ORR, overall response rate; PR, partial response; sCR, stringent complete response; VGPR, very good partial response

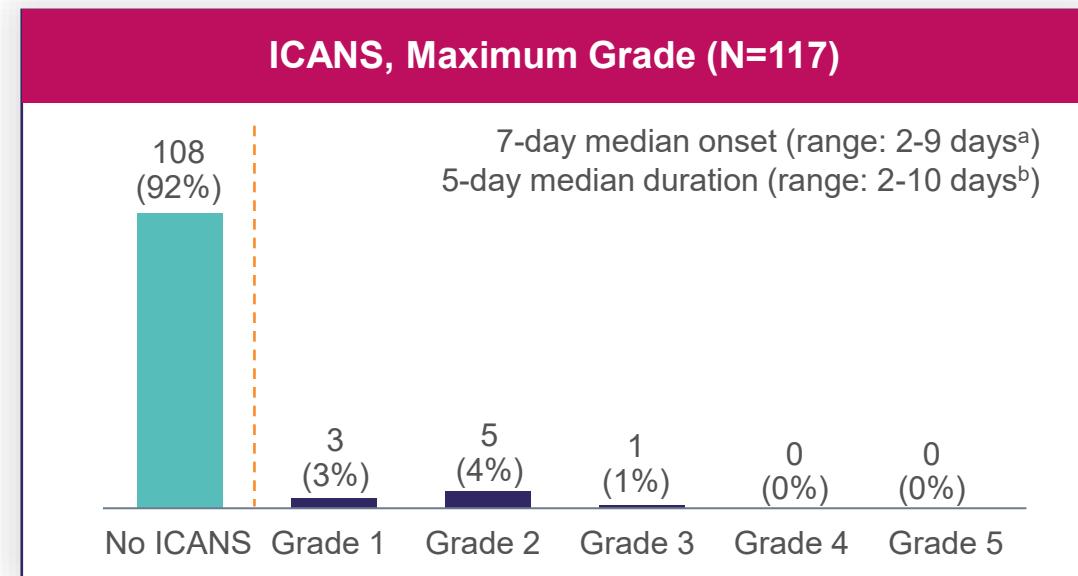
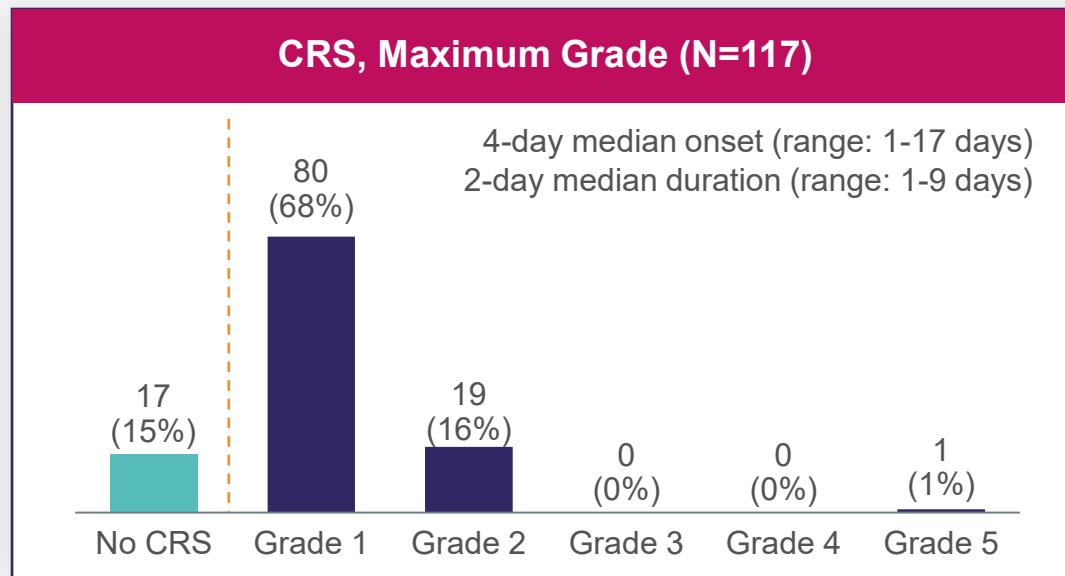
iMImagine-1: PFS and OS Rates Estimated by Kaplan-Meier

Median PFS and OS were not reached

N=117	PFS Rate (%) (95% CI)	OS Rate (%) (95% CI)
6-Month	93.1 (86.7, 96.5)	95.7 (90.0, 98.2)
12-Month	82.1 (73.6, 88.1)	94.0 (87.8, 97.1)
18-Month	67.4 (55.4, 76.8)	88.0 (78.8, 93.4)
24-Month	61.7 (48.0, 72.8)	83.0 (70.7, 90.5)

Median follow-up of 15.9 months (range: 0.3 – 33.1 months)
PFS, progression-free survival; OS, overall survival

iMImagine-1: Safety Update



- 95% (111/117) of patients had either no CRS or CRS that resolved by ≤ 10 days of anito-cel infusion
- No new treatment-related or treatment-emergent deaths have occurred since the previous May 1, 2025 datacut
- No secondary primary malignancies of T-cell origin have occurred
- No replication competent lentivirus detected

No delayed or non-ICANS neurotoxicities, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome, and no immune effector cell-associated enterocolitis have been observed to date at ≥ 10 months since anito-cel infusion

^aWith the exception of n=1 Grade 1 ICANS (confusion) on day 31 post infusion that rapidly resolved. ^bWith the exception of n=1 max Grade 2 ICANS with 29-day duration to resolution
Note: Updates to data resulting from ongoing data review; CRS and ICANS assessed per American Society for Transplantation and Cellular Therapy criteria
CRS, cytokine release syndrome; ICANS, immune-effector cell-associated neurotoxicity syndrome

Safety and Efficacy of AZD0120, a BCMA/CD19 Dual-Targeting CAR T-cell Therapy, in Relapsed/Refractory Multiple Myeloma: Preliminary Results From the DURGA-1 Phase 1b/2 Study

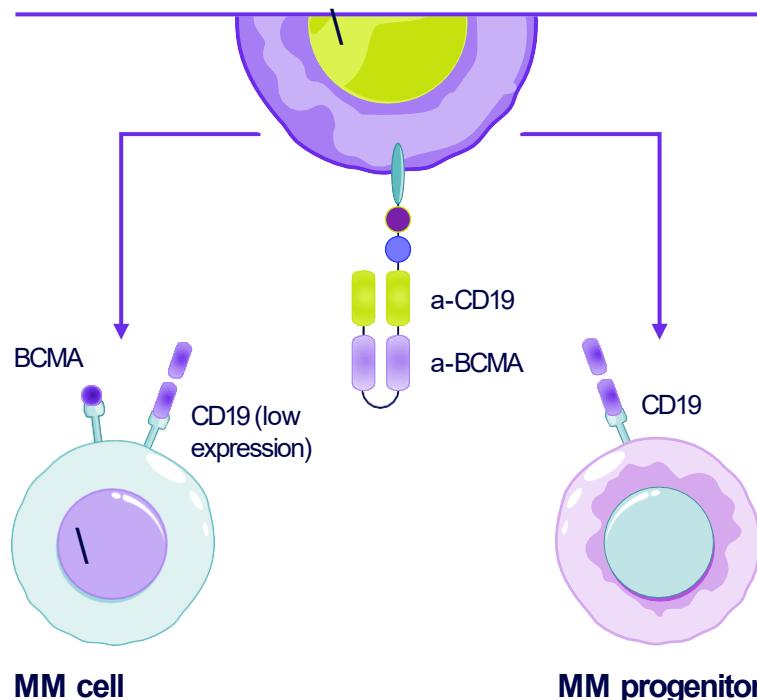
Shambavi Richard, MD¹, Mahmoud Gaballa, MMBCh², Tara Gregory, MD³, Saurabh Chhabra, MD, MS⁴, Larry D. Anderson Jr, MD, PhD⁵, Luciano J. Costa, MD, PhD⁶, Caitlin Costello, MD⁷, Scott R. Goldsmith, MD⁸, Doris K. Hansen, MD⁹, Sridevi Rajeeve, MD¹⁰, Shaji Kumar, MD¹¹, Aravind Ramakrishnan, MD¹², Minoo Battiwalla, MD, MS¹³, Ajay K. Nooka, MD, MPH¹⁴, Hira Shaikh, MBBS¹⁵, Meiyue G. Hong, MD¹⁶, Steven Wang, MS¹⁷, Patricia Cheung, PhD¹⁸, Liang Li, PhD¹⁹, Binod Dhakal, MD²⁰

¹Icahn School of Medicine at Mount Sinai, New York, NY; ²The University of Texas MD Anderson Cancer Center, Houston, TX; ³Colorado Blood Cancer Institute, Denver, CO; ⁴Mayo Clinic Arizona, Phoenix, AZ; ⁵Hematologic Malignancies and Cellular Therapy Program, Simmons Comprehensive Cancer Center, UT Southwestern Medical Center, Dallas, TX; ⁶University of Alabama at Birmingham, Birmingham, AL; ⁷University of California San Diego Moores Cancer Center, San Diego, CA; ⁸City of Hope Comprehensive Cancer Center, Duarte, CA; ⁹Moffitt Cancer Center, Tampa, FL; ¹⁰Memorial Sloan Kettering Cancer Center, New York, NY; ¹¹Mayo Clinic, Rochester, MN; ¹²Sarah Cannon Transplant and Cellular Therapy, St. David's South Austin Medical Center, Austin, TX; ¹³Sarah Cannon Transplant and Cell Therapy Network, Nashville, TN; ¹⁴Winship Cancer Institute of Emory University, Atlanta, GA; ¹⁵University of Iowa Hospital & Clinic, Iowa City, IA; ¹⁶AstraZeneca, Boston, MA; ¹⁷AstraZeneca, Mississauga, Canada; ¹⁸AstraZeneca, South San Francisco, CA; ¹⁹AstraZeneca, Gaithersburg, MD; ²⁰Medical College of Wisconsin, Milwaukee, WI

AZD0120: A Novel BCMA/CD19 Dual CAR T

Dual Target

BCMA/CD19 Dual CAR T



Next-Generation Manufacturing

Faster to Patients

Manufactured in
<3 days

Better T Cells

Younger, fitter naive T cells

Safety profile enabling
outpatient administration
and monitoring

Making cell therapy available to
more patients

AZD0120 was formerly named GC012F, and next-generation manufacturing refers to the FasTCAR platform.
BCMA, B-cell maturation antigen; CART, chimeric antigen receptor T-cell therapy; MM, multiple myeloma.

CRS and ICANS

CRS	DL1 (n=12)	DL2 (n=14)	Total (n=26)
CRS, overall	9 (75%)	7 (50%)	16 (62%)
Grade 1	9 (75%)	6 (43%)	15 (58%)
Grade 2	0	1 (7%)	1 (4%)
Grade 3+	0	0	0
Onset time, median (range), days	9 (2–11)	9 (8–10)	9 (2–11)*
Duration, median (range), days	1 (1–4)	2 (1–2)	1.5 (1–4)
CRS management			
Tocilizumab	7 (58%)	5 (36%)	12 (46%)
Dexamethasone	1 (8%)	2 (14%)	3 (12%)
Anakinra	0	1 (7%)	1 (4%)

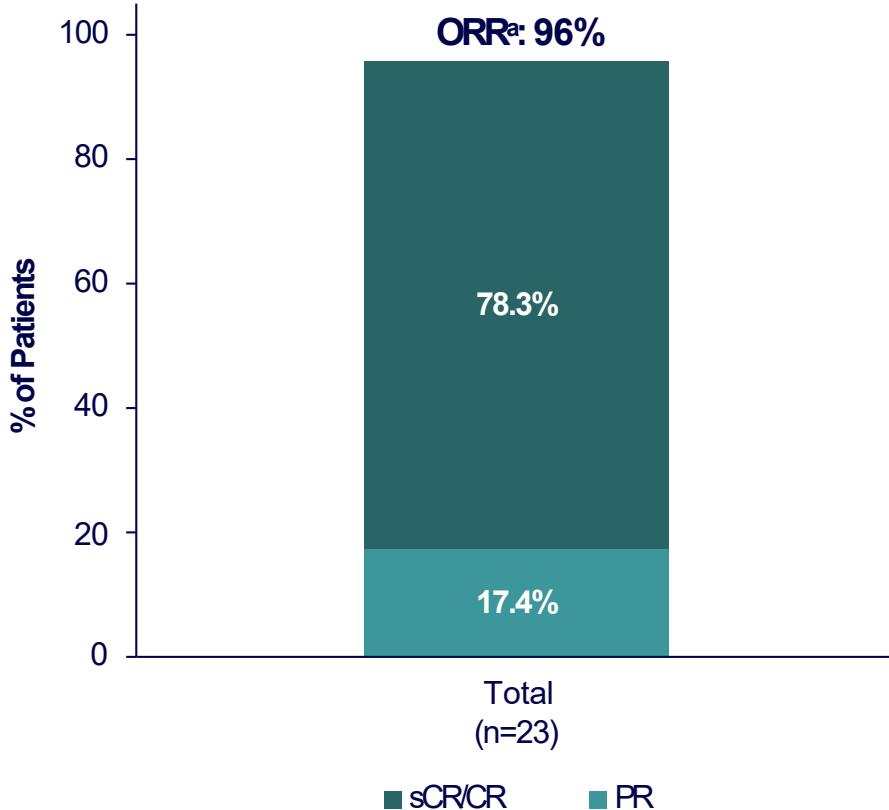
- No grade 3+ CRS reported
- *CRS onset on day 8–11 for 15 of 16 patients

ICANS	DL1 (n=12)	DL2 (n=14)
ICANS, overall	0	1 (7%)
Grade 1	0	1 (7%)
Grade 2	0	0
Grade 3+	0	0
Onset time, days	NA	10
Duration, day	NA	1

- No delayed neurotoxicities, including no Parkinsonism, no cranial nerve palsies, and no Guillain-Barré syndrome reported
- No IEC-associated colitis reported
- Only one grade 1 ICANS event
- One patient with IEC-HS (DL1, grade 2); resolved within 7 days

CRS, cytokine release syndrome; DL, dose level; IEC, immune effector cell; IEC-HS, immune effector cell–associated hemophagocytic lymphohistiocytosis-like syndrome; ICANS, immune effector cell–associated neurotoxicity syndrome; NA, not applicable.

Efficacy: 96% ORR, 78% CR



- Median follow-up time = 3.9 months
- Median time to first response = 28 days
- Responses deepened over time

	Total (n=23)	BCMA CAR T Exposed (n=5)
ORR	96%	100%
sCR/CR	78%	80%
Follow-up, median (range), months	3.9 (0.9–19.7)	3.9 (3.0–4.0)

Efficacy-evaluable population defined as all patients who received conformed AZD0120 infusion at the targeted DL with measurable disease at baseline and at least one post-baseline efficacy assessment.

^aResponse as assessed by study investigator using IMWG criteria.

BCMA, B-cell maturation antigen; CART, chimeric antigen receptor T-cell therapy; CR, complete response; DL, dose level; IMWG, International Myeloma Working Group; ORR, objective response rate; PR, partial response; sCR, stringent complete response.

Efficacy and Safety of Talquetamab + Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma and Extramedullary Disease: Updated Phase 2 Results From the RedirecTT-1 Study With Extended Follow-Up

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¹Memorial Sloan Kettering Cancer Center, New York, NY, USA; ²Mayo Clinic Rochester, Rochester, MN, USA; ³University Hospital of Salamanca/IBSAM/CIC/CIBERONC, Salamanca, Spain;

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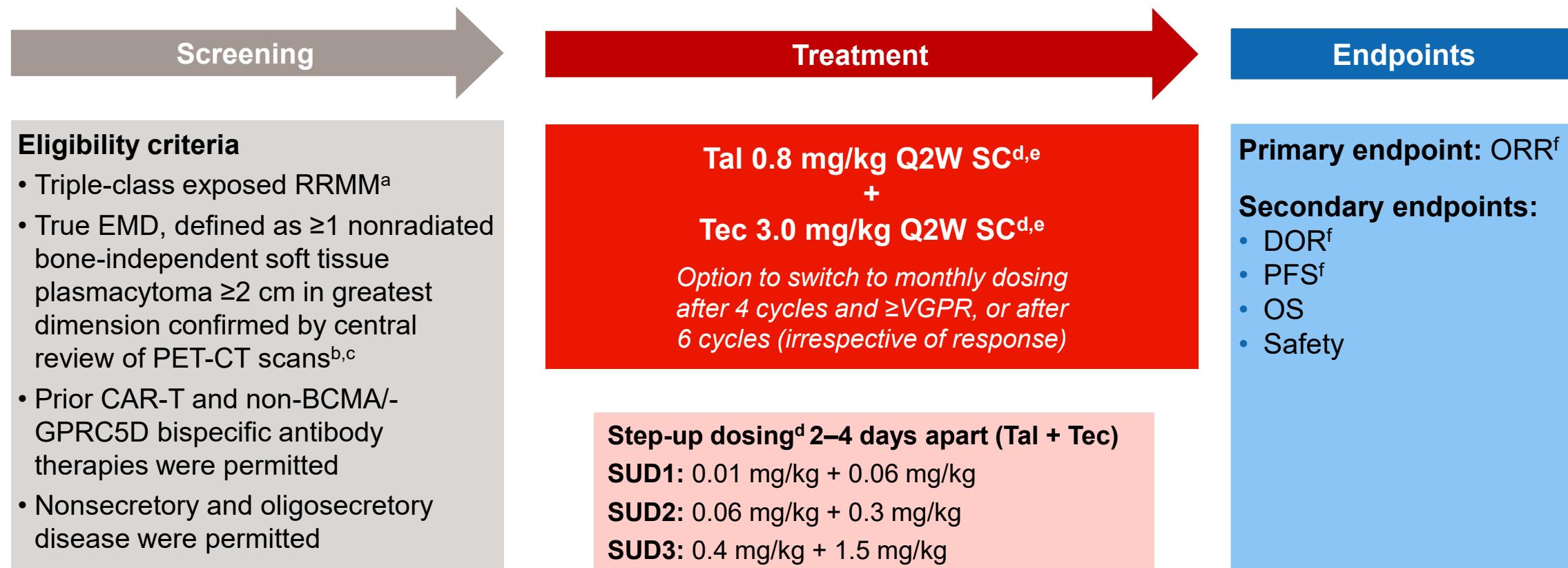
*Contributed equally.

<https://www.congresshub.com/ASH2025/Oncology/Talquetamab/Usmani>

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RedirecTT-1 Phase 2 EMD (Tal + Tec): Largest Dedicated Study in Patients With True EMD

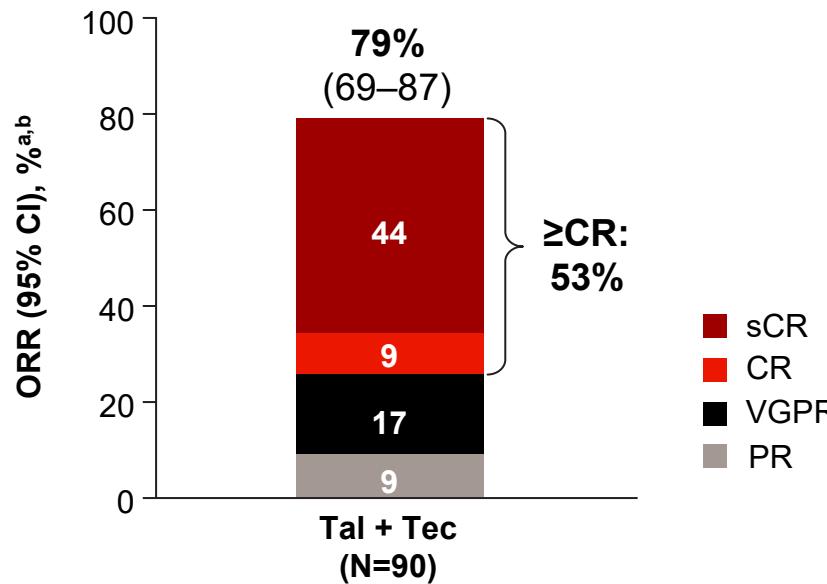


^aIncludes prior exposure to a proteasome inhibitor, immunomodulatory drug, anti-CD38 monoclonal antibody. ^bPatients may have had paramedullary plasmacytomas in addition to true EMD. ^cWhole-body MRI permitted with sponsor approval. ^dTal and Tec administered on the same day, 30 (± 10) minutes apart, for all step-up and full treatment doses. ^eUntil disease progression. ^fResponse and PFS were assessed by an independent review committee per IMWG criteria; EMD response was assessed by PET-CT or MRI whole-body scans. CAR, chimeric antigen receptor; DOR, duration of response; MRI, magnetic resonance imaging; PET-CT, positron emission tomography-computed tomography; Q2W, every other week; SC, subcutaneous; SUD, step-up dose; VGPR, very good partial response.

Kumar S, et al. *N Engl J Med* 2025; doi:10.1056/NEJMoa2514752.

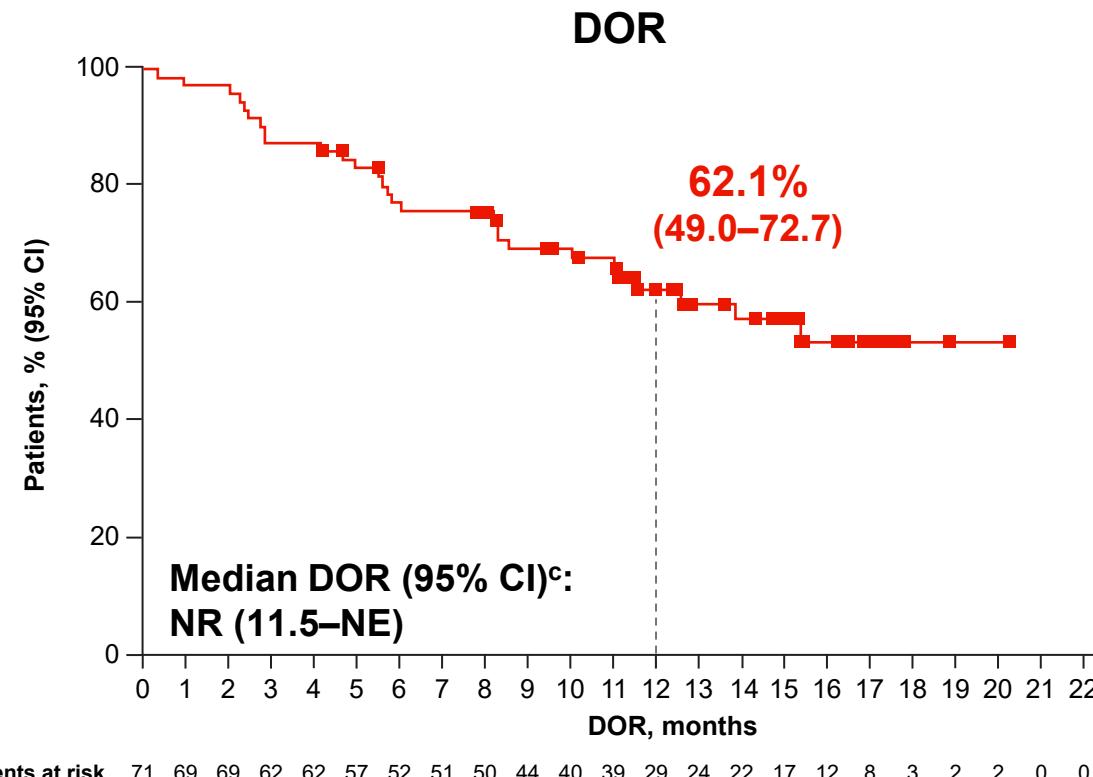


RedirecTT-1 Phase 2 EMD (Tal + Tec): Deep, Durable Responses at 16.8 Months Median Follow-up



Median (range) time to:

- First response, 2.6 (1.0–5.8) months
- Best response, 5.1 (1.0–16.6) months

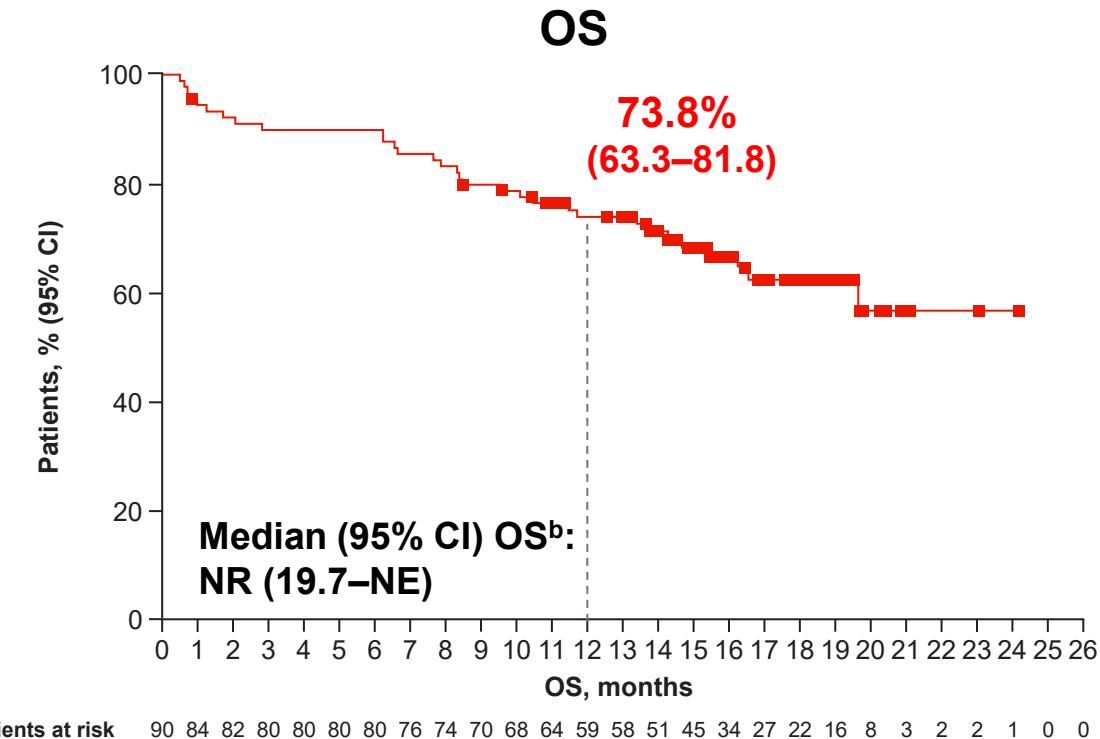
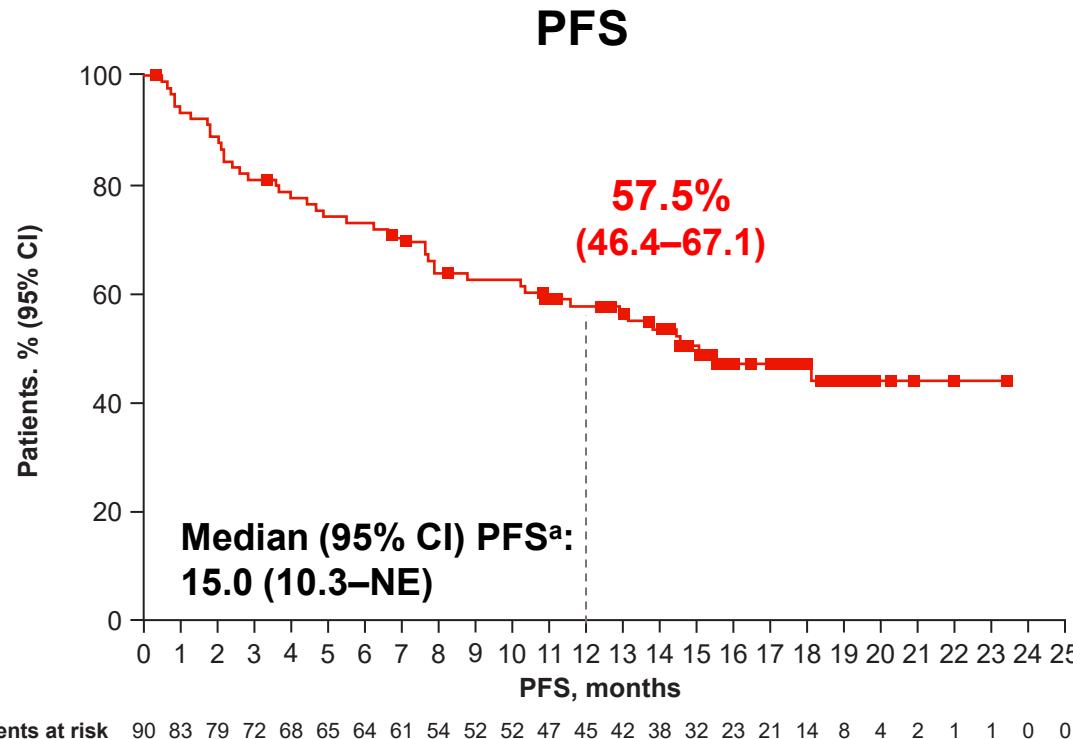


With additional ~4 months of median follow-up, ORR approached 80%;
62% of responders remained in response at 1 year

Data cut-off date: July 18, 2025. ^aORR was assessed by independent review committee per IMWG criteria. ^bDue to rounding, individual response rates may not sum to the ORR. ^cAt time of data cut-off, 43 (60.6%) patients were censored. NE, not estimable; NR, not reached; sCR, stringent complete response.



RedirecTT-1 Phase 2 EMD (Tal + Tec): PFS and OS at 16.8 Months Median Follow-up



With over 1 year of median follow-up, median PFS was 15 months and median OS was not reached

Data cut-off date: July 18, 2025. ^aAt time of data cut-off, 45 (50.0%) patients were censored for PFS. ^bAt time of data cut-off, 59 (65.6%) patients were censored for OS.

Presented by S Usmani at the 67th American Society of Hematology (ASH) Annual Meeting; December 6–9, 2025; Orlando, FL, USA



Etentamig Plus Pomalidomide-Dexamethasone Combination Therapy in Relapsed or Refractory Multiple Myeloma: A Phase 1b Dose-Escalation and Safety Expansion Study

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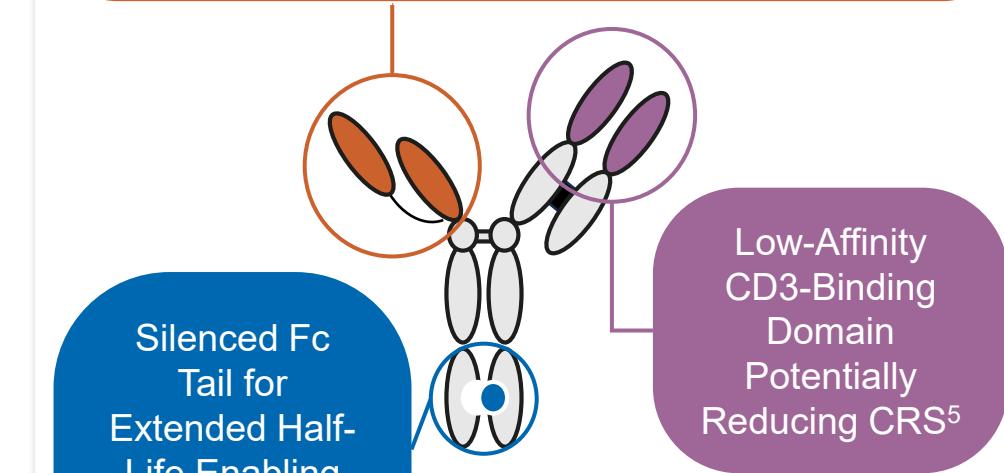
Etentamig is a next-generation differentiated BCMA x CD3 bispecific T-cell engager

Long-term results from 2 ongoing Phase 1 studies (NCT03933735/NCT05650632) of Etentamig in heavily pretreated patients with RRMM demonstrate^{1,2}:

- 30% overall CRS rate
 - Grade 1: 26%
 - Grade 2: 4%
 - No Grade 3+ events
- Deep and durable responses with 66% ORR
- Convenient treatment schedule, including Q4W dosing

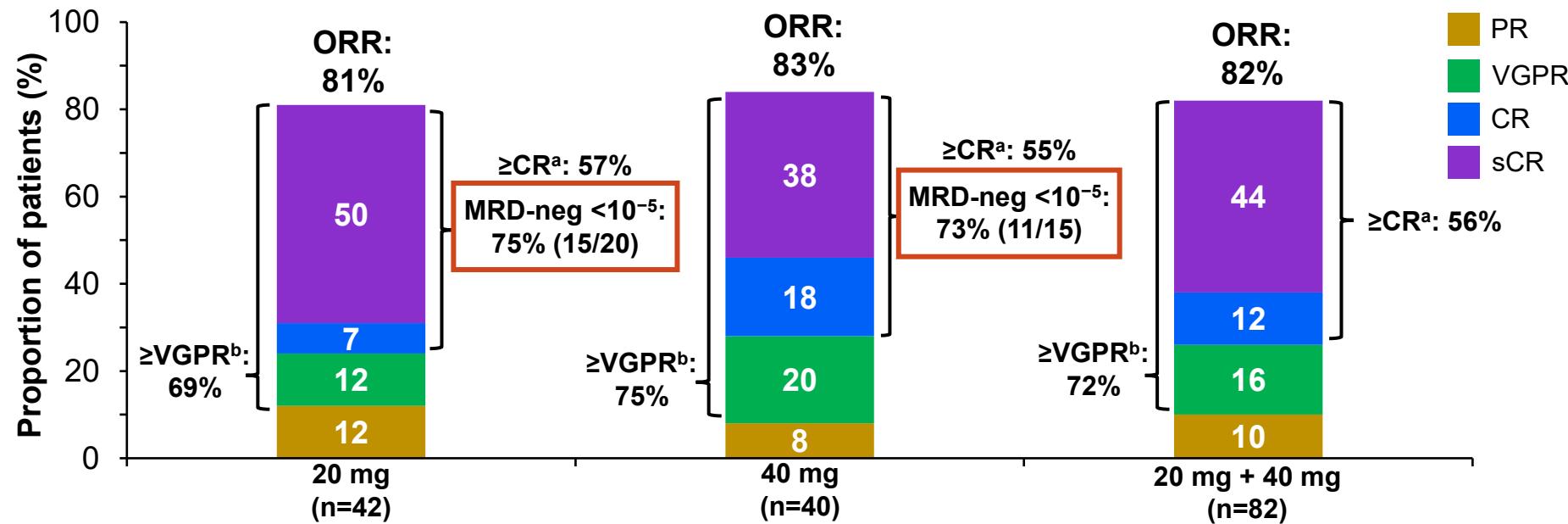
Preclinical data demonstrate enhanced Etentamig activity when used in combination with antimyeloma regimens, including IMiD agents^{3,4}

Bivalent BCMA-Binding Domain With High Avidity to Promote T-Cell Mediated Killing and Activation⁵



Here we present data on Etentamig in combination with Pom + dex from Arm A (safety and efficacy) and Arm E (safety) of the Kilimanjaro study (NCT05259839) in patients with RRMM

Arm A: Etentamig combined with Pom + dex led to deep responses in heavily pretreated RRMM patient population



Months (range)	Arm A: Etentamig + Pom + dex		
	20 mg (n=44)	40 mg (n=41)	20 mg + 40 mg (N=85)
Median follow up	27 (1–33)	19 (1–26)	23 (1–33)
Median time to first response ^c	1 (1–19)	1 (1–9)	1 (1–19)
Median time to CR	7.0 (3, 21)	6 (3, 16)	7 (3, 21)

Responses in the 40 mg cohort may deepen further with continued follow-up

^a≥CR: sCR+CR. ^b≥VGPR: VGPR+CR+sCR. ^cTime to response is the time from the date of first dose to the date of first documented PR or better determined by 2016 IMWG criteria. CR, complete response; dex, dexamethasone; IMWG, International Myeloma Working Group; MRD, minimal residual disease; ORR, overall response rate; Pom, pomalidomide; PR, partial response; RRMM, relapsed or refractory multiple myeloma; sCR, stringent complete response; VGPR, very good partial response.

Brief Takeaways On Late Relapse

1. *in vivo* CAR T holds promise for effective CAR T therapy more easily and safely delivered in MM
2. Anitocel and AZD0120 are novel CAR T products with high efficacy and lower risk of neurological toxicities
3. The combination of teclistamab and talquetamab is very potent in EMD
4. Etentamig is a novel bispecific antibody that may be delivered more easily in the community

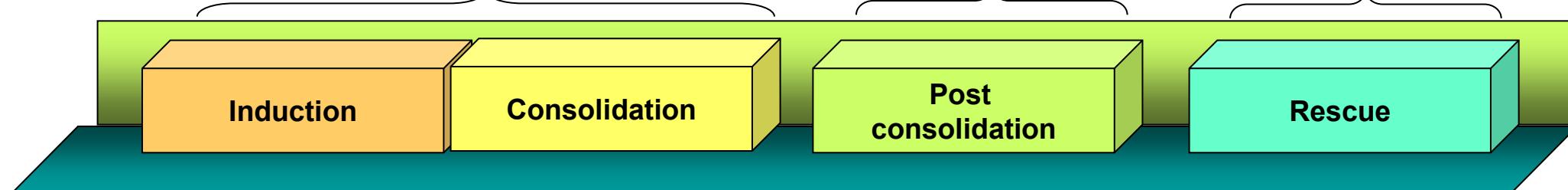
The Evolution of Myeloma Therapy – MORE to come!

Now

VTD
VRD
KRD
D-VMP
DRD
D-VRD
D-KRD
Isa-KRD

SCT +/- More induction

Front line treatment



New

Belantamab
or Bispecifics?

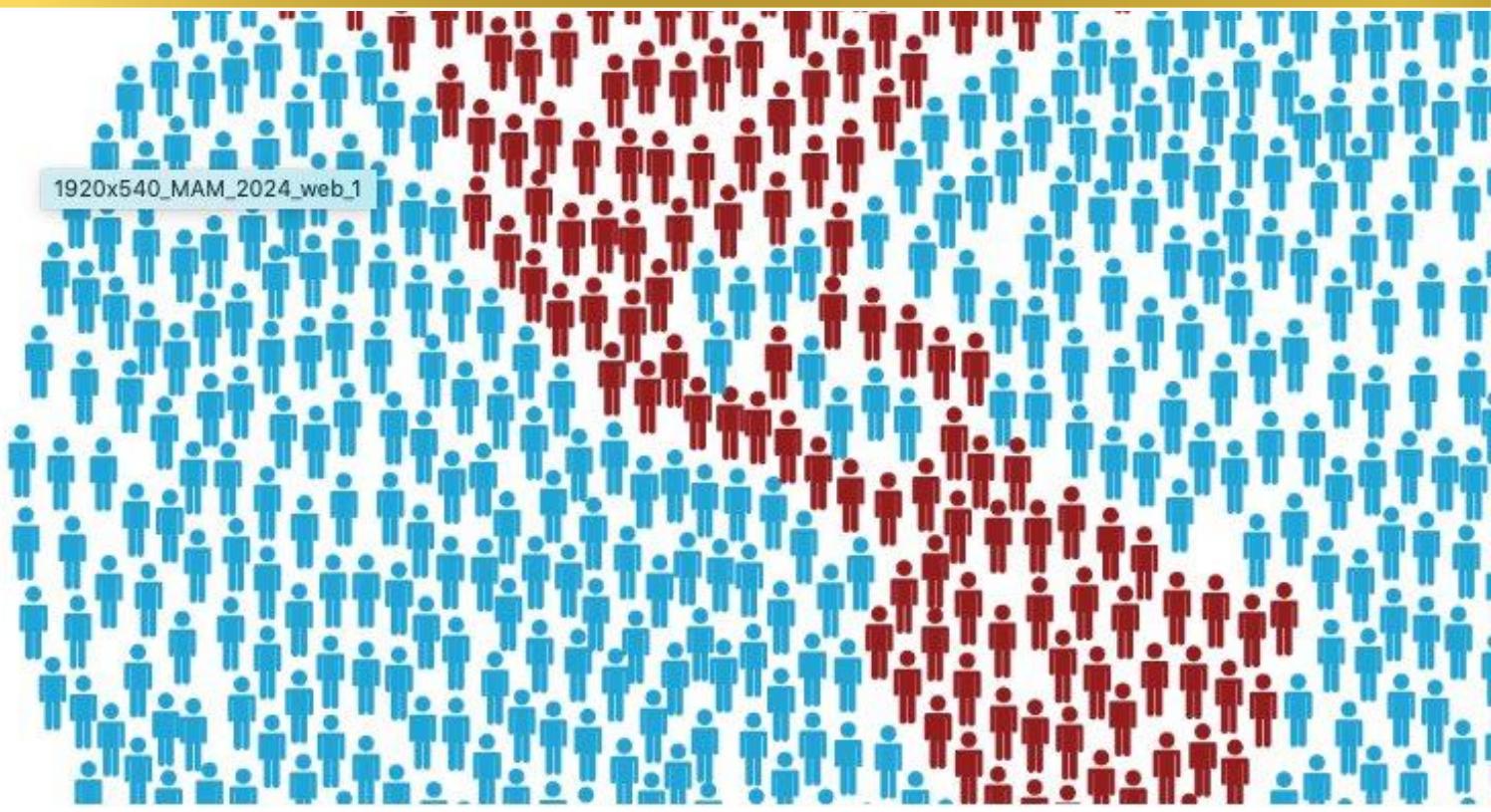
CAR T or Bispecifics?

Iberdomide,
Belantamab or
Bispecifics?

Novel CAR T Cell Therapies
Bispecific/Trispecific Antibodies
Iberdomide and Mezigdomide
Venetoclax/Sonrotoclax for t(11;14)?
Multiple small molecules

MYELOMA ACTION MONTH

#MYELOMAACTIONMONTH

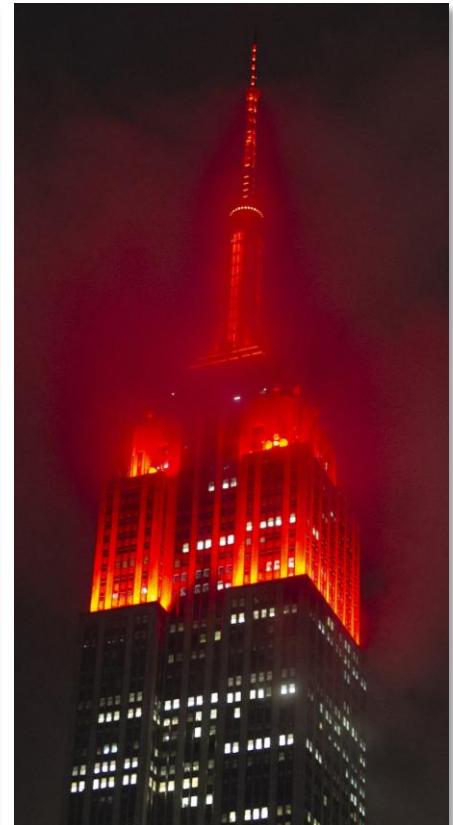
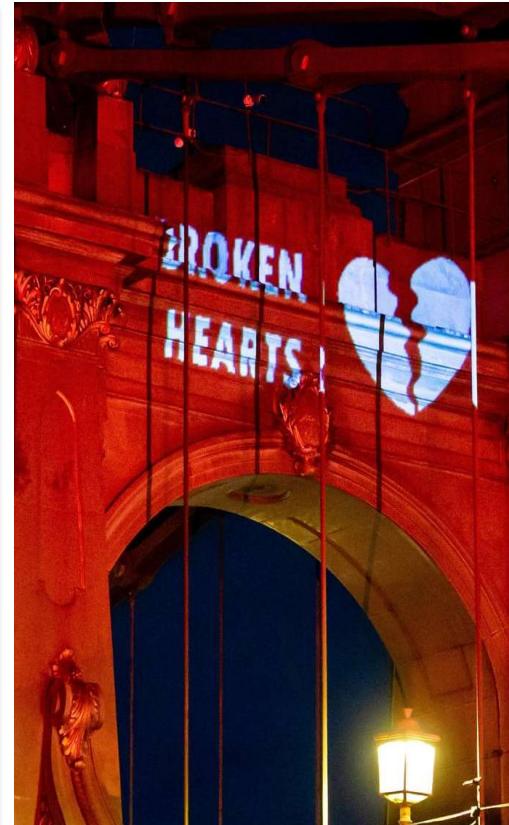
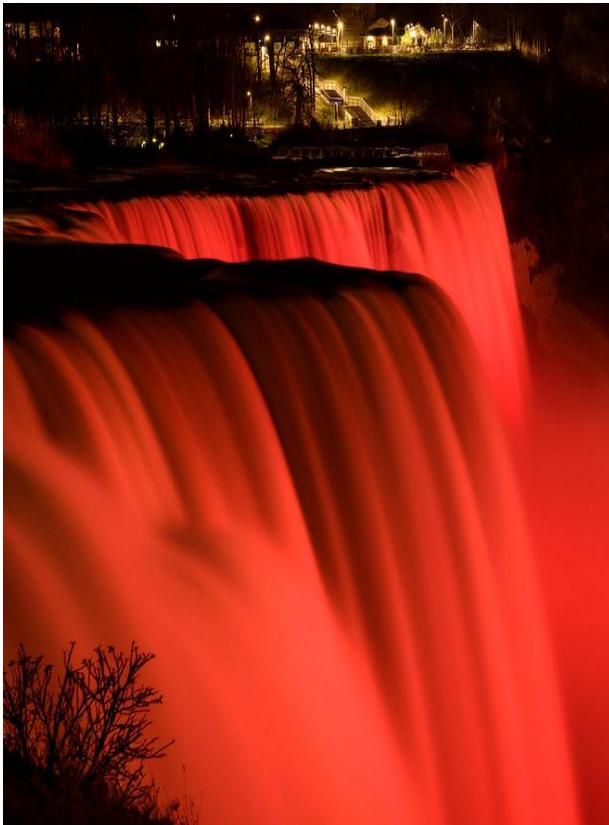


Myeloma Action Month is a **global social awareness** campaign that takes place every March to **raise awareness of multiple myeloma**. We urge the community to **champion Myeloma Action Month** to help make a **positive impact on those suffering** from this blood cancer.

Will you take action for the myeloma community?

LIGHT THE WORLD RED! MAM 2026

Our goal is to light as many landmarks globally as we can in the color red to bring awareness to myeloma. Everyone can help with this initiative-let us know if you reach out to landmarks so we can keep track of all of the lightings!



OUR VISION:

A world where every myeloma patient can live life to the fullest, unburdened by the disease.

OUR MISSION:

Improving the quality of life of myeloma patients while working toward prevention and a cure.